

# **MEDICARE PRESCRIPTION DRUG BENEFIT**

## **Solicitation for Applications from Cost Plan Sponsors**

**January 21, 2005**

(as revised March 9, 2005)

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#### **1. GENERAL INFORMATION**

### **1.1 Purpose of Solicitation**

The Centers for Medicare and Medicaid Services is seeking applications from qualified section 1876 Cost HMOs/CMPs (hereinafter referred to as “cost plan sponsors” or “Applicant”) to enter into a contract to offer Medicare Prescription Drug Plans (PDPs) as described in the Medicare Prescription Drug Benefit Plan Final Rule as published in the Federal Register. Please submit your applications according to the process described in Section 2.0.

### **1.2 Background**

The Medicare Prescription Drug Benefit program was established by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and is codified in section 1860D-1 through 1860 D-41 of the Social Security Act (the Act). Section 101 of the MMA amended Title XVIII of the Social Security Act by redesignating Part D as Part E and inserting a new Part D, which establishes the Voluntary Prescription Drug Benefit Program (hereinafter referred to as “Part D”).

### **1.3 Objectives and Structure**

The new Part D benefit constitutes perhaps the most significant change to the Medicare program since its inception in 1965. The addition of outpatient drugs to the Medicare program reflects Congress’ recognition of the fundamental change in recent years in how medical care is delivered in the U.S. It recognizes the vital role of prescription drugs in our health care delivery system, and the need to modernize Medicare to assure their availability to Medicare beneficiaries. Effective January 1, 2006, the Part D program establishes a voluntary prescription drug benefit for individuals who are entitled to Medicare Part A or enrolled in Part B.

In general, coverage for the new prescription drug benefit will be provided predominately through private at-risk prescription drug plans that offer drug-only coverage, or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans). PDPs must offer a basic drug benefit. MA-PD plans must offer either a basic benefit or broader coverage for no additional cost. Medicare cost plans and PACE organizations may, at their election, offer a Part D drug plan in the same manner as an MA-PD plan. If the MA-PD plan meets the basic requirement, then it may also offer additional drug benefits through enhanced alternative coverage for an additional premium. For cost plans, even for the basic Part D benefit, the drug benefit will be an optional supplemental benefit.

Applicants who offer either a PDP or MA-PD plan may offer national (i.e. offering a plan in every region) or regional plans. MA-PD plan Applicants may also offer local plans. CMS has identified 26 MA Regions and 34 PDP Regions, not including territories, in

which PDPs or regional MA-PDs may be offered. Additional information about the regions can be found at <http://www.cms.hhs.gov/medicarereform/mmaregions>. Cost plans are local plans and are not required to provide regional coverage. However, the local area that a cost plan covers is counted toward whether a fallback area exists.

The MMA requires that each region have at least two Medicare prescription drug plans from which to choose, and at least one of those must be a PDP. In areas, where the required minimum number of plan choices is not available, the MMA requires CMS to contract with Fallback Entities. Fallback Entities must satisfy the same requirements as PDPs, but will receive reimbursement for drug costs from CMS on a cost rather than a risk basis. This solicitation is only for entities seeking to operate a Part D supplemental benefit in addition to their cost plan. Separate Part D solicitations are also posted on the CMS website, for entities offering MA Plans with a Part D Drug benefit at the local or regional levels and for at risk PDPs. Solicitations for PDP and MA-PD products for employer groups will be released later in 2005, as will a solicitation for Fallback Plans for potential Fallback regions, if any. A separate Part D solicitation for PACE organizations will be released later in 2005. PDP Applicants or subcontractors acting as an integral part of the drug benefit management activities for the PDP may not apply to offer a Fallback Plan.

Part D sponsors will have flexibility in terms of benefit design. This flexibility includes, but is not limited to, authority to establish a formulary that designates specific drugs that will be available within each therapeutic class of drugs, and the ability to have a cost-sharing structure other than the statutorily defined structure (subject to certain actuarial tests). (Plans would still be required to follow our formulary guidance. See Section 2.7.1 of this application). The plans also may include supplemental drug coverage such that the total value of the coverage exceeds the value of basic prescription benefit coverage.

Payment for qualified drug benefits is separate from interim and settlement cost payments cost plans sponsors receive for Part A and/or Part B services under their cost contract agreements. CMS will provide payment to cost plans sponsors in the form of advance monthly payments, reinsurance subsidies (when incurred), and low-income subsidies. Further detail on payment for Part D services is provided in Section 2.6 of this document.

As stated above, Section 1876 cost contractors are not required to offer a Part D benefit to their enrollees. Section 1876 cost contractors may offer qualified prescription drug coverage as an optional supplemental benefit under 42 CFR 417.440(b)(2). Further, Section 1876 cost contractors may offer enhanced prescription drug coverage, but only if they offer the basic Part D benefit to their enrollees as well. Section 1876 cost plan enrollees may or may not choose to elect to receive their Part D benefits through their Medicare cost plan. They may instead elect to enroll in a PDP to receive prescription drug benefits.

#### **1.4 Schedule**

<b>APPLICATION REVIEW PROCESS</b>	
<b>Date</b>	<b>Milestone</b>
January 19, 2005	Registration Closes for Pre-Application Conferences in Baltimore
January 21, 2005	Posting of Part D solicitations on CMS website
January 21, 2005	Registration Closes for Pre-Application Conferences in San Diego and New Orleans
January 24 – 27, 2005	Pre-Application Conference – Baltimore
January 31 – February 1 2005	Pre-Application Conference – San Diego
February 3 – 4, 2005	Pre-Application Conference – New Orleans
February 18, 2005	Request HPMS Access (Includes User ID and Password Request), if not already established
March 23, 2005	Applications due
May/June 2005	CMS sends Part D contract eligibility determination to Applicants, based on review of application. Applicant's bids must still be negotiated (see below)

<b>FORMULARY BID AND CONTRACTING PROCESS</b>	
<b>Date</b>	<b>Milestone</b>
April 4 -5, 2005	CMS conducts Bid and Formulary Training Conference in Washington D.C.
March 28 - April 18, 2005	Applicants submit formularies to CMS for review
April 8, 2005	Applicants receive instructions to download Plan Benefit Package and Pricing Tool software from the Health Plan Management System (HPMS).
May 16, 2005	CMS provides preliminary approval of formularies
May 20, 2005	CMS begins accepting bid submissions via HPMS
June 6, 2005	Qualified Applicants submit bids to CMS via HPMS for each of the Part D plans they propose to offer during 2006. Disapproved Applicants requesting a reconsideration of CMS' determination must submit their bids on this date as well.
June 6 - July 25, 2005	Modifications to bids accepted only at the discretion of CMS
Late July 2005	Training on submission of drug claims data to CMS
July 15, 2005	Any favorable redetermination, including those resulting from a hearing or Administrator review must be made for the contract in question to be effective on January 1 of the following year.
Early August 2005	CMS publishes national average Part D premium
September 2, 2005	CMS completes review and approval of bid data. CMS executes Part D addendum to Cost Plan contracts with Cost Plan Sponsors who submit an acceptable bid.

<b>PRE-IMPLEMENTATION AND IMPLEMENTATION PROCESS</b>	
<b>Date</b>	<b>Milestone</b>
January 2005	Begin weekly Part D Applicant/Sponsor technical support calls with

	CMS
March 23, 2005	Submit contact and other related information to HPMS
March 28, 2005	CMS plans to release the formulary upload functionality
April 2005	Marketing guidelines posted on CMS website
April/May 2005	Reporting requirements posted on CMS website in April except data requirements for price compare will be available in May
April 2005	Enrollment requirements posted on CMS website
April 8, 2005	CMS plans to release the HPMS bid creation functionality, including the PBP and BPT software
April 18, 2005	Formularies are due to CMS
April 18, 2005	Responses to Quality Assurance and Patient Safety and Medication Therapy Management Program questions are due to CMS
April 20, 2005	Details regarding submitting pricing and pharmacy network information to be posted on <a href="http://www.cms.hhs.gov">www.cms.hhs.gov</a> by this date
May 20, 2005	CMS plans to release the PBP and BPT upload functionality
May 20 – June 6, 2005	Applicants can submit bid uploads to HPMS
Early Summer 2005	Establish Connectivity to AT&T Medicare Data Network (MDCN)
June 7, 2005	Part D sponsors submit electronic test data to CMS
July 2005	CMS releases Coordination of Benefits requirements
Summer 2005	Submit <i>Banking Information Form</i> (Appendix II)
Summer 2005	Begin testing between Part D sponsors and CMS on information systems interfaces and data exchanges
July 29, 2005	Part D sponsors submit corrected test data electronically to CMS
August 2005	Re-evaluation of pharmacy access requirements
September 2005	Training on Certification Enrollment and Payment Submit <i>Certification of Monthly Enrollment and Payment Data Relating to CMS Payment</i> (Appendix V)
September 16, 2005	Part D sponsors submit actual data to CMS electronically for final testing
October 6, 2005	Part D sponsors submit data that will be published on <a href="http://www.medicare.gov">www.medicare.gov</a>
November 15, 2005	Part D initial enrollment period begins for individuals who are first eligible to enroll in a Part D plan on or prior to January 31, 2006
January 1, 2006	Medicare beneficiaries begin receiving drug benefits from Medicare Part D contractors
January 1, 2006	Auto-enrollment effective for beneficiaries who are full-benefit dual eligible as of December 31, 2005.
May 15, 2006	Initial enrollment period ends for individuals who are first eligible to enroll in a Part D plan on or prior to January 31, 2006

NOTE: CMS reserves the right to amend or cancel this solicitation at any time. CMS also reserves the right to revise the Medicare Prescription Drug Benefit program implementation schedule, including the solicitation and bidding process timelines.

### **1.5 Summary of Cost Plan Sponsor Role and Responsibilities**

Key aspects of each cost plan shall include the ability to:

- Submit a formulary each year for CMS approval.
- Submit a Part D plan bid each year for CMS approval.
- Enroll in their Part D plan all eligible Medicare beneficiaries who apply and reside within the cost plan sponsor's approved service area.
- Administer the Part D benefit, including providing coverage for drugs included in a CMS-approved formulary, administering appropriate deductibles and co-payments, managing the benefit using appropriate pharmacy benefit managerial tools, and operating effective oversight of that benefit.
- Provide access to negotiated prices on covered Part D drugs, with different strengths and doses available for those drugs, including a broad selection of generic drugs.
- Ensure that records are maintained in accordance with CMS rules and regulations and that both records and facilities are available for CMS inspection and audit.
- Disclose the information necessary for CMS to oversee the program and ensure appropriate payments.
- Offer a contracted retail pharmacy network, providing convenient access to retail pharmacies.
- Process claims at the point of sale.
- Operate quality assurance, drug utilization review, and medication therapy management programs.
- Administer a coverage determinations, grievances, exceptions, and appeals process consistent with CMS requirements.
- Provide customer service to beneficiaries, including enrollment assistance, toll-free telephone customer service help, and education about the Part D benefit.
- Protect the privacy of beneficiaries and beneficiary-specific health information.
- Develop marketing materials and conduct outreach activities consistent with CMS standards for completeness, appropriateness, and understandability.

- Develop and/or maintain systems to support enrollment, provide claims-based data to CMS, accept CMS payment (including subsidies for low-income beneficiaries), track true out-of-pocket costs, coordinate benefits with secondary insurers (or primary insurers when Medicare is secondary), and support e-prescribing.
- Provide necessary data to CMS to support payment, oversight, and quality improvement activities and otherwise cooperate with CMS oversight responsibilities.

## **1.6 Summary of CMS Role and Responsibilities**

### ***Application Approval, Part D Bid Review, and Contracting Processes***

There are three distinct phases to the overall review to determine whether CMS will enter into a contract with an Applicant. The first phase, is the application review process. CMS will review all applications submitted on or by March 23, 2005 to determine whether the Applicant meets the qualifications we have established to enter into a Part D addendum to the Applicant's cost contract.

The second phase has two steps – the formulary review which begins April 18, 2005 and the bid review which begins June 6, 2005. The formulary review entails determining that the proposed formulary (if one is used) has at least two drugs in every therapeutic category and class (unless special circumstances exist that would allow only one drug) does not substantially discourage enrollment by certain types of Part D eligible individuals; includes adequate coverage of the types of drugs most commonly needed by Part D enrollees; and includes an appropriate transition policy. CMS will contact Applicants if any issues are identified during the review for discussion and resolution. The intent is to provide an opportunity for Applicants to make any necessary corrections prior to Part D bid submission on June 6, 2005. The second step involves the bid review and negotiations with plans to assure valuation of the proposed benefits are reasonable and actuarially equivalent.

The third phase involves contracting. Applicants judged qualified to enter into a Part D addendum as a result of successfully completing phase one and two will be offered a Part D contract by CMS.

### ***Part D Program Oversight***

CMS will develop a Medicare Prescription Drug Benefit program monitoring system to ensure that the plans deliver good value through defined benefits and are compliant with program requirements. This monitoring system will be developed in coordination with the CMS personnel responsible for oversight of the Cost Plans to minimize duplication of effort. We will focus on several operational areas critical to the value of the benefit, including beneficiary access to and satisfaction with their Part D benefit and protection of the financial integrity of the program. Specific areas will include pharmacy access, adequacy and value of the benefit, benefit management, enrollment and disenrollment, marketing, program safeguard activities, customer service, confidentiality and security of enrollee information, and effectiveness of tracking true out-of-pocket expenses. The types

of the reporting that CMS will require of Part D sponsors is presented in the application. Further detail on our approach to monitoring and oversight, including the exact reporting measures will be posted on the CMS website no later than April 2005. (*NOTE: Part D sponsors, as covered entities under the Privacy Rule, are subject to investigation and penalties for findings of Privacy Rule violations as determined by the Department of Health and Human Services Office for Civil Rights and the Department of Justice.*) We will monitor, through the analysis of data we collect from Part D sponsors, CMS contractors, and our own systems. The types of data we expect to collect from sponsors include: certain benefit data, claims data, cost data, benefit management data, marketing review information, and customer satisfaction and complaints data.

To monitor plan performance in the areas we have identified, we will: 1) conduct beneficiary satisfaction surveys and operate a complaints tracking system to monitor and manage complaints brought to our attention that are not satisfactorily resolved through Part D sponsors' grievance processes; and 2) conduct periodic site visits to verify Part D sponsor compliance with Part D program requirements. We will use information from all the specified sources to analyze the appropriateness and value of the benefit delivered, and to evaluate the opportunity for additional value and quality improvement. If any trends we identify indicate less than satisfactory performance, significant departures from the marketed Part D offering, or fraud or other violations of State or Federal laws, appropriate action will be taken ranging from request for corrective action plans to all categories of sanctions consistent with 42 CFR 423.509 and Part 423, Subpart O. We also will make referrals if appropriate to the Services Office of the Inspector General, or to Federal and State authorities where violations of laws under the jurisdictions of these agencies are in question.

### ***Education and Outreach***

CMS is committed to educating Medicare beneficiaries about the Part D program. CMS plans to educate beneficiary and consumer groups, health care providers, States, and other interested groups about the Part D program. Among the topics to be discussed with these groups is the identification and reporting of possible fraud and/or abuse. CMS may also engage in other activities that publicize or otherwise educate beneficiaries about the program.

### ***Marketing Guidelines and Review***

CMS is developing marketing guidelines and expects to post them on the CMS web site as a separate document from this solicitation no later than April 2005. Part D sponsors are required to adhere to these guidelines in developing their marketing materials and marketing strategy. We will retain a contractor to provide technical assistance in the development of these guidelines and review materials submitted by plans in accordance with statutory requirements. Cost plan sponsors are required to submit materials to CMS based on the marketing guidelines.

### ***Eligibility for the Low Income Subsidy Program***

Low-income Medicare beneficiaries will receive full or partial subsidies of premiums and reductions in cost sharing under the Part D benefit. Certain groups of Medicare

beneficiaries will automatically be eligible for the low-income subsidy program. These beneficiaries include full-benefit dual eligible individuals, Medicare beneficiaries who are recipients of Supplemental Security Income benefits, and participants in Medicare Savings Programs as Qualified Medicare Beneficiaries (QMBs), Specific Low-Income Medicare Beneficiaries (SLMBs), and Qualifying Individuals (QIs). Beneficiaries who are low-income and who do not fall into one of the automatic subsidy eligibility groups will apply for a low-income subsidy and have their eligibility determined by either the Social Security Administration (SSA) or the states. We will develop a database to track individuals who are automatically deemed subsidy-eligible or who are determined subsidy-eligible by SSA or the states, and communicate the names and eligibility category of those individuals to plan sponsors as part of the enrollment files from the enrollment processing system described below.

### ***General Enrollment Processing***

CMS has developed a system to review an individual's eligibility to enroll a Part D plan. For individuals applying for enrollment in a Part D plan, CMS will review an individual's status as a Medicare beneficiary. We will track enrollments and ensure enrollment exclusivity. CMS will also track low-income subsidy status and the auto-enrollment of full-benefit dual eligible beneficiaries into Part D plans. Finally, CMS will track disenrollments from Part D plans and will deny new enrollments during any given year unless the enrollment occurs during an allowable enrollment period.

### ***Payment to Cost Plan Sponsors***

CMS will provide payment to cost plan sponsors in the form of advance monthly payments (consisting of the Part D standardized bid, risk adjusted for health status, minus the beneficiary monthly premium), estimated reinsurance subsidies, and estimated low-income subsidies. After the end of the payment year, CMS will reconcile the correct amounts of low-income subsidies and reinsurance amounts against the amount paid as a part of the prospective monthly payments. Risk sharing amounts (if applicable) will be determined after all other reconciliations have been completed. For a more complete description refer to Prescription Drug Event Data at [www.cms.hhs.gov/pdps/PrescriptionDrugEventDataPaper.pdf](http://www.cms.hhs.gov/pdps/PrescriptionDrugEventDataPaper.pdf).

## **2. INSTRUCTIONS**

### **2.1 Overview**

This application is to be completed only by those section 1876 cost plan contractors that intend to offer a Part D benefit to their cost plan enrollees during 2006. This application is to be submitted in conjunction with your organization's attestation to renew your cost contract with CMS in 2006. Please refer to the guidance for transitioning MA and Cost Plans posted on the CMS web site for instructions on the documentation your organization must provide to CMS to qualify to offer Part A and/or Part B benefits during 2006.

### **2.2 Pre-Application Conferences**

CMS will conduct three conferences for potential Medicare Advantage (MA), Cost Plan and Prescription Drug Plan (PDP) sponsors to learn about requirements for plans under the MMA. The following conferences are planned:

- January 24-27, 2005 in Baltimore , Maryland
- January 31-February 1, 2005 in San Diego, California ; and
- February 3-4, 2005 in New Orleans , Louisiana

The Baltimore conference is a four-day technical assistance and guidance conference for the Medicare Advantage and Prescription Drug industries on the new opportunities available under the Medicare Prescription Drug, Improvement, and Modernization Act. The conference will be conducted January 24-27, 2005 at the Radisson Lord Baltimore Hotel, Baltimore, Maryland. The conference will include sessions on the prescription plan drug and Medicare Advantage applications processes, regional PPOs, and employer group options. The training for potential drug benefit sponsors will be focused on completing the application. CMS strongly encourages the new and transitioning PACE programs, along with those with demonstration projects to attend the Baltimore conference. Information regarding registration, accommodations and other details for this conference can be accessed at <http://cms.c2ti.com/industry>. Registration closes for this conference on January 19, 2005.

In addition, conferences have also been scheduled for January 31-February 1 in San Diego and for February 3-4 in New Orleans for the convenience of PDP and MA representatives who are unable to attend the January 24-27, 2005 Industry Conference in Baltimore. These two conferences will have very similar content to the Baltimore conference but will be conducted with simultaneous PDP and MA sessions. Consequently, organizations that wish to hear about both MA and PDP at these conferences should plan to send two staff to cover both sessions. Information regarding registration, accommodations and other details for the San Diego and New Orleans

conferences can be accessed at [www.aspenxnet.com/partd](http://www.aspenxnet.com/partd). Registration closes for these two conferences on January 21, 2005.

Please note that the San Diego and New Orleans conferences will cover the same PDP topics presented in Baltimore; however, the field conferences will not cover some MA topics such as appeals rules that are largely unchanged by the Medicare Modernization Act, but may nonetheless be of interest to potential new MA contractors. These topics will be covered in the Baltimore conference only. Therefore, CMS strongly encourages new MA organizations to attend the Baltimore conference.

### **2.3 Other Technical Support**

CMS will conduct weekly technical support calls for Applicants from January 19, 2005 through June 2005, followed by bi-weekly calls. CMS operational experts (e.g. enrollment, information systems, marketing, bidding, formulary design, and coordination of benefits) will be available to discuss and answer questions on the agenda items for each meeting. Registration for the technical support calls can be found at [www.aspenxnet.com/partd/usergroups](http://www.aspenxnet.com/partd/usergroups).

### **2.4 Instructions and Format of Qualifications**

#### ***Instructions***

In preparing your application in response to the prompts in Section 3.0 of this solicitation, please mark “Yes” or “No” in sections organized with that format.

In many instances Applicants are directed to affirm that they will meet particular requirements by indicating “Yes” next to a statement of a particular Part D program requirement. By providing such attestation, an Applicant is committing its organization to complying with the relevant requirements as of September 15, 2005, unless an alternative date is noted in Section 3.0.

Additional supporting documentation is notated in the following manner throughout the application and is to be submitted as follows:

1. Appendices: documents supplied by CMS that are contained at the end of this application. They are to be completed by the Applicant and returned to CMS as indicated.
2. Attachments – documents that are to be created and/or supplied by the Applicant and sent to CMS with the application. Attachments are to be used only when the application does not indicate to respond directly below the question. (i.e. Pharmacy Lists, subcontracts, etc.)

More specifically, Pharmacy Lists requested in Section 3.4, should only be submitted electronically on a Computer Diskette (CD) using Microsoft Excel (*see Format section below for instructions on creating the CDs and Section 3.4 for specific information on*

*creating the pharmacy lists*). Due to the amount of data - hard copies of these lists should not be included with the application.

Legal documents such as subcontracts should be provided in hard copy as an attachment to the application. They should also be provided on the CD associated with the relevant application section. The CD identification should include the appendix number.

CMS will check the application for completeness shortly after its receipt. We will notify Applicants of any deficiencies and afford them the opportunity to amend their applications.

While cost plan sponsors are not required to begin providing the Part D benefit until January 1, 2006, CMS has established the September 15, 2005 deadline to allow adequate time for sponsors to cure any operational deficiencies before beneficiaries become entitled to Part D services. As with all aspects of a Part D sponsor's operations under its contract with CMS, we may verify a sponsor's compliance with qualifications it attests it will meet, through on-site visits at the sponsor's facilities as well as through other program monitoring techniques. Failure to meet the requirements attested to in the Applicant's response to this solicitation and failure to operate its Part D plan(s) consistent with the requirements of the applicable statutes, regulations, and the Part D contract may delay a Part D sponsor's marketing and enrollment activities or, if corrections cannot be made timely, disqualify it from participation in the Part D program.

An individual with legal authority to bind the Applicant shall sign and submit the certification found in Section 4.0. CMS reserves the right to request clarifications or corrections to a submitted application. Failure to provide requested clarifications within a 2-day period could result in the Applicant receiving an intent to deny the application, in which case, the Applicant will then have 10 days to seek to remedy its application.

This solicitation does not commit CMS to pay any cost for the preparation and submission of an application.

***Format***

- To assure that each CMS review panelist receives the application in the manner intended by the Applicant, Applicants should deliver a total of four (4) hard copies of the written application and supporting documentation.
- All hard copies should be in separate 3-ring binders. Tab indexing should be used to identify all of the major sections of the application. Page size should be 8 ½ by 11 inches and the pages should be numbered. Font size should be 12 point.
- One application should be clearly marked, "Original" and contain all original signed certifications requested in the application.

- Additionally, the Applicant must submit the written application and supporting documentation electronically using (CDs). This will support the review of the application by different CMS components. The Applicant must submit 4 sets of the 5 CDs identified below. Each set should be inserted inside of each hard copy application being submitted.

CD NUMBER	CONTENTS ON CD
CD #1	Entire Application and Supporting Documentation – including Appendices, and Attachments ( <i>Do Not Include Pharmacy Lists</i> )
CD #2	Subsection 3.1.1 and Subsection 3.1.2 and related Appendices and Attachments
CD #3	Subsection 3.1.3 and Section 3.10 and related Appendices and Attachments
CD #4	Section 3.3 and related Appendices and Attachments (includes Pharmacy Lists)
CD #5	Section 2.11 and related Attachments

- All responses should be completed in Microsoft Word (in a version that is compatible with Office 2003). Attachments (such as existing contracts) can be submitted in Microsoft Word (in a version that is compatible with Windows 2003) or as a PDF file. Pharmacy lists should be created in Microsoft Excel (in a version that is compatible with Office 2003).
- Each CD must be clearly labeled with the information in the table below:

<b>Applicant's Organization Name</b>
<b>CMS Identification Number</b>
<b>CD Number (as notated above)</b>
<b>Section and/or Subsection Number and Name</b>

- Failure to submit an application consistent with these instructions may delay its review by CMS.
- Applications must be sent to:  
Centers for Medicare & Medicaid Services (CMS)  
Marietta Mack  
Media Center  
Attn: Cost Plan - Part D Application  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850
- Applications mailed through carriers that do not have CMS Security Clearance could be delayed due to clearance processing. Carriers with CMS Security Clearance include Federal Express and Airborne Express.
- CMS will not review applications received after 5:00 P.M. EST on March 23, 2005.

### ***Single Application Representing Multiple Plans***

Part D Plans of the same type, offered by the same legal entity, regardless of their service area may be represented in a single application. There are three types of Part D solicitations for which applications are due on March 23, 2005; they are PDP, MA-PD, and Cost Plan solicitations. Entities that intend to offer a combination of these types of Part D plans must submit a separate application for each type. (Employer and PACE plan sponsors will also have separate solicitations.) For example, an MA-PD and PDP product may not be represented in the same application. Also, entities intending to offer both local MA-PD and Regional PPO plans must submit separate MA-PD applications. If an Applicant's response to any inquiry in the application is different for one plan than another, this delineation must be clearly identified at the beginning of each section of the application where such delineation is made. The Applicant must use consistent nomenclature to distinguish between the plans as necessary throughout the application. The Applicant must submit a face sheet to the application indicating that multiple plans are represented in the application, whether plan-specific delineations are made, the nomenclature to distinguish among the plans, and in what sections and subsections of the application.

### ***Applicant Entity Same as Contracting Entity***

The legal entity that submits this application must be the same entity with which CMS enters into a Part D contract, or in the case of an MA-PD and Cost Plan sponsor, the same legal entity seeking an addendum to an MA or Cost Plan contract. An entity that qualifies for a Part D contract, or for an addendum to an MA or Cost Plan contract, may offer multiple plans of the same type (e.g. PDP, MA-PD, or Cost Plan) in the service area described in the application.

## **2.5 Submission Software Training**

Applicants will use the CMS Health Plan Management System (HPMS) during the application, formulary, and bid processes. Applicants will be required to enter contact and other related information collected in HPMS in order to facilitate the application review process.

Applicants will be required to upload their plan formularies to HPMS using a pre-defined file format and record layout. CMS plans to release the formulary upload functionality on March 28, 2005. Formularies are due to CMS on April 18, 2005.

In order to prepare plan bids, Applicants will use HPMS to define their plan structures and associated plan service areas and then download the Plan Benefit Package (PBP) and Bid Pricing Tool (BPT) software. For each plan being offered, Applicants will use the PBP software to describe the detailed structure of their Part D benefit and the BPT software to define their bid pricing information. The formulary must accurately crosswalk to the PBP. The combination of the PBP and BPT for a plan comprises a bid. CMS anticipates releasing the HPMS bid creation functionality, including the PBP and BPT software, on April 8, 2005.

Once the PBP and BPT software has been completed for each plan being offered, Applicants will upload their bids to HPMS. CMS anticipates releasing the PBP and BPT bid upload functionality on May 20, 2005. Applicants will be able to submit bid uploads to HPMS on their PBP or BPT one or more times between May 20, 2005 and the CY 2006 bid deadline of June 6, 2005. CMS will use the last successful upload received for a plan as the official bid submission.

CMS will provide technical instructions and guidance upon release of the HPMS formulary and bid functionality as well as the PBP and BPT software. In addition, systems training will be available at the Bid Training in April 2005.

## **2.6 System and Data Testing with CMS**

### ***HPMS***

Cost plan sponsors will use HPMS to communicate with CMS in support of the application process, formulary submission process, bid submission process, ongoing operations of the Part D program, and reporting and oversight activities. Cost plan sponsors are required to secure access to HPMS in order to carry out these functions. As current contractors, Cost Plan sponsors may already have access to HPMS.

If a Cost Plan sponsor does not currently have HPMS access, then the Applicant should refer to *Instructions for Accessing CMS Systems* (Appendix I) for instructions on establishing access to HPMS. Establishing connectivity will ensure that Applicants have sufficient time to prepare and submit their formularies to HPMS by April 18, 2005 and their PBPs and BPTs by June 6, 2005.

### ***Enrollment***

Cost plan sponsors will be required to establish connectivity to CMS via the AT&T Medicare Data Communications Network (MDCN). This secure network allows direct transmission of enrollment information to CMS for processing.

- CMS recommends that cost plan sponsors contact AT&T to establish connectivity 3 months prior to beginning file transmissions.
- AT&T can be contacted on 1-800-905-2069.
- Cost plan sponsors must also obtain a CMS User ID and password.
- Download the User Access Form located at [www.cms.hhs.gov/mdcn/access.pdf](http://www.cms.hhs.gov/mdcn/access.pdf), complete it and mail it to your assigned CMS plan manager.

CMS will communicate a beneficiary's eligibility for enrollment in a Part D plan as well as for a low-income subsidy. CMS will also determine whether a beneficiary must pay a late enrollment penalty. CMS will record the results of this processing and reply to the

cost plan sponsor. Monthly membership listings will be made available for reconciliation purposes. They will be downloaded using the MDCN connectivity. Similarly, cost plan sponsors will be required to report disenrollment information to CMS.

A test environment will be established to accept, process, and reply to cost plan sponsor Part D transmissions. In addition, Help Desk staff will be available to assist cost plan sponsors in this process and to trouble-shoot reported problems. Testing is expected to occur during the summer of 2005. Specific instructions will be provided prior to that time.

#### ***Payment – Cost Plan Sponsors***

Payments to cost plan sponsors for their Part D services will be wired to sponsor accounts on the first business day of each month (or the last business day of the prior month if the first day of the month is not a business day). As current contractors, Cost Plans may have already established accounts for CMS payment. Cost Plan sponsors that wish to make changes to their existing arrangements must submit the *Banking Information Form* (Appendix II) so that payments can be transmitted to the sponsor's account.

The monthly payment will include premiums that SSA or other agencies are deducting from beneficiary Social Security payments as well as those premiums CMS is paying on behalf of low-income individuals. Estimated monthly reinsurance subsidies, and low-income subsidies will also be included.

Monthly beneficiary-level payment reports will be available detailing the components of each payment for reconciliation purposes. Cost plan-level reports summarizing the monthly payment and any applicable adjustments will also be provided. Cost plans will download these reports via their MDCN connectivity.

Test versions of these reports will be provided in late summer of 2005. Specific testing instructions will be provided at a later date.

### **2.7 Summary Instruction and Format for Part D Bids**

Cost plan sponsors must submit to CMS a bid for each prescription drug plan it intends to offer. Applicants using this solicitation may apply to offer full risk Part D plans only. Applicants must submit their formularies to HPMS on or before April 18, 2005 and the PBPs and BPTs on or before June 6, 2005.

### **2.7.1 Format of Part D Bids**

#### ***Bid Submission Sections Due Prior to June 6, 2005***

To facilitate the timely review of all the bid submissions, CMS expects to require Applicants to submit the portion of their bid related to formulary and covered drugs by April 18, 2005. CMS will review areas of each proposed drug plan formulary by tier and drug availability and evaluate each element against evidence-based standards such as widely accepted treatment guidelines. Elements will include, but may not be limited to the list of drugs, the categories and classes, tier structures (not cost sharing), and utilization management tools such as quantity limits, step therapy, and prior authorization. CMS will make the review criteria available to Applicants well in advance of the date Applicants must submit this information to CMS. Outliers will be selected for further review of the formulary development process prior to CMS approval of the bid. CMS will make reasonable efforts to inform Applicants of their outliers so that they may substantiate their offering. If such substantiation is not satisfactory to CMS, the Applicant will be given the opportunity to modify the formulary. CMS intends to complete as much of this work as possible before the June 6, 2005, PBP and BPT submissions so that any modification may be reflected in those documents.

#### ***Bid Submission Due June 6, 2005***

The Applicant's bid will represent the expected monthly cost to be incurred by the Applicant for qualified prescription drug coverage in the approved service area for a Part D-eligible beneficiary on a standardized basis. The costs represented in each bid should be those for which the Applicant would be responsible. These costs would not include payments made by the plan enrollee for deductible, coinsurance, co-payments, or payments for the difference between the plan's allowance and an out-of-network pharmacy's usual and customary charge. The bid will require the separate identification, calculation, and reporting of costs assumed to be reimbursed by CMS through reinsurance. CMS requires that the bid represent a uniform benefit package based upon a uniform level of premium and cost sharing among all beneficiaries enrolled in the plan. The benefit packages submitted must be cross walked appropriately from the formulary. Pursuant to 423.505(k)(4), the CEO, CFO, or a delegatee with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information and belief) that the information in the bid submission, and assumptions related to projected reinsurance and low-income cost sharing subsidies, is accurate, complete, and truthful, and fully conforms to the requirements in section 423.265 of the regulations. In addition, the pricing component of the bid must also be certified by a qualified actuary.

### **2.7.2 CMS Review of Part D Bids**

CMS will evaluate the bids based on four broad areas: 1) administrative costs, 2) aggregate costs, 3) benefit structure, and 4) plan management. CMS will evaluate the

administrative costs for reasonableness in comparison to other bidders. CMS will also examine aggregate costs to determine whether the revenue requirements for qualified prescription drug coverage are reasonable and equitable. In addition, CMS will review the steps the PDP sponsor is taking to control costs, such as through various programs to encourage use of generic drugs. Finally, CMS will examine indicators concerning plan management, such as customer service.

CMS is also required to make certain that bids and plan designs meet statutory and regulatory requirements. We will conduct an actuarial analysis to determine whether the proposed benefit meets the standard of providing qualified prescription drug coverage. Also, CMS will review the structure of the premiums, deductibles, co-payments, and coinsurance charged to beneficiaries and other features of the benefit plan design to ensure that it is not discriminatory (that is, that it does not substantially discourage enrollment by certain Part D eligible individuals).

### **2.7.3 Overview of Part D Bid Negotiation**

CMS expects to evaluate the reasonableness of bids submitted by Cost Plan sponsors by means of an actuarial valuation analysis. This requires evaluating assumptions regarding the expected distribution of costs, including average utilization and cost by drug coverage tier. CMS could test these assumptions for reasonableness through actuarial analysis and comparison to industry standards and other comparable bids. Bid negotiation could take the form of negotiating changes upward or downward in the utilization and cost per script assumptions underlying the bid's actuarial basis. CMS could exercise our authority to deny a bid if we do not believe that the bid and its underlying drug prices reflect market rates.

## **2.8 Standard Contract with Cost Plan Sponsors**

Successful Applicants will be deemed qualified to enter into a Part D addendum to the its section 1876 cost plan contract allowing the Applicant to operate a Medicare prescription drug plan(s) as an optional supplemental benefit. Only after the qualified Applicant and CMS have reached agreement on the Applicant's bid submissions will the Applicant be asked to execute its Part D addendum.

The Part D addendum will be for an initial 16-month term (September 1, 2005 through December 31, 2006), renewable after the initial term for one-year periods at the end of each calendar year at the option of both CMS and the Applicant. The initial 16-month contract period is intended to ensure that cost plan sponsors meet enrollment and marketing requirements prior to the January 1, 2006 start date of the first Part D benefit period. CMS expects to provide a draft of the addendum in Spring 2005.

## **2.9 Additional Information Available**

To assist Applicants in preparing the retail pharmacy network access analysis, CMS has posted a data file at <http://www.cms.hhs.gov/pdps/> that contains total Medicare beneficiary counts by ZIP code. This file also includes markers for MA and PDP regions. The file name is "MCareEnrbyZip062004.zip."

To assist Applicants in preparing their long-term care (LTC) pharmacy access analysis, CMS has provided Applicants with a data file at <http://www.cms.hhs.gov/pdps/> that contains information on LTC facility location (address, state, zip code, MA region, and PDP region) and certified bed count. The file name is "LTCFacilities012005.zip."

To assist Applicants in preparing their bids, CMS has made the following drug use and drug spending information available at <http://www.cms.hhs.gov/pdps/> :

- Individual-level data from the Medicare Current Beneficiary Survey (MCBS)
- Continuance tables based on MCBS data
- Medicaid data based on 48 states
- State-level expenditure adjusters based on Federal retirees in a national plan; Medicaid drug expenditure data for most states
- Drug costs imputed from the MCBS to a 5 percent sample of Medicare beneficiaries

## **2.10 Protection of Confidential Information**

Applicants can always seek to protect their information under the Freedom of Information Act and label truly proprietary information "confidential" or "proprietary." When information is so labeled, the Applicant is required to explain the applicability of the FOIA exemption they are claiming. When there is a request for information that is designated by the Applicant as confidential or that could reasonably be considered exempt under Exemption 4, CMS is required by its FOIA regulation at 45 C.F.R. §5.65(d) and by Executive Order 12,600 to give the submitter notice before the information is disclosed. To determine whether the Applicant's information is protected by Exemption 4, the Applicant must show that— (1) disclosure of the information is likely to impair the government's ability to obtain necessary information in the future; (2) disclosure of the information is likely to cause substantial harm to the competitive position of the submitter; or (3) the records are considered valuable commodities in the marketplace which, once released through the FOIA, would result in a substantial loss of their market value. Consistent with our approach under the Medicare Advantage program, we would not release information under the Medicare Part D program that would be considered proprietary in nature.

## **2.11 Waivers**

CMS is authorized to grant waivers of Part D program requirements otherwise applicable to cost plans, where such a requirement conflicts with or duplicates a requirement under Section 1876 (or 42 CFR Part 417), or where granting such a waiver would improve the cost plan sponsor's coordination of Part A and B and Part D benefits. Accordingly, CMS has identified the waivers it is granting to all cost plan sponsors in the chart shown in *Summary of PDP Application Requirements Waived for Cost Plan Prescription Drug Applicants* (Appendix IV). As a result of the CMS-granted waivers, the cost plan sponsor application is less comprehensive than the PDP sponsor application. These waivers will be reflected in each cost plan sponsor's Part D addendum.

*Applicant Requests for Additional Waivers:* CMS may grant additional waivers upon an cost plan sponsor's request, provided that the waivers may be justified as duplicative of or conflicting with section 1876 cost plan requirements, or improving the coordination of Part A and/or Part B benefits with Part D benefits. Any waiver granted by CMS will apply to all similarly situated cost plan sponsors. For each waiver request, the Applicant must provide, as an attachment to its cost plan sponsor application and on a CD per instructions in Section 2.4, a statement that includes:

1. The Part D regulation reference;
2. The appropriate waiver criteria (e.g., duplicative, conflicts, improves benefit coordination);
3. A discussion of how the requested waiver meets at least one of the three waiver criteria.

CMS will notify Applicants whether their requests were approved as part of the notice of cost plan sponsor application approval they will receive in May 2005. As noted above, waivers granted will be reflected in each cost plan sponsor's Part D addenda.

Where this application directs the Applicant to attest that it will meet a particular Part D requirement for which the Applicant has requested a waiver, the Applicant should check both the "Yes" box and the "Waiver Requested" box. In the event that CMS does not approve a particular waiver, the Applicant will still have attested that it will meet all the applicable Part D program requirements and remain eligible to enter into a Part D addendum upon approval of its bids at the end of the summer of 2005. This process will prevent Applicants from having to submit additional application responses after the original March 23, 2005 deadline. If, as a result of CMS' denial of its waiver request, the Applicant no longer intends to offer a Part D benefit plan, the Applicant must notify CMS in writing on or before June 30, 2005. CMS will not execute a Part D addendum with Applicants that submit such a notice. The notice should be sent to:

Centers for Medicare & Medicaid Services (CMS)  
Center for Beneficiary Choices  
Attention: Marietta Mack  
Mail Stop S1-25-13/Location S2-04-05  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

### 3. APPLICATION

Note: Nothing in this application is intended to supersede the regulations at 42 CFR Part 423. Failure to reference a regulatory requirement in this application does not affect the applicability of such requirement, and Cost Plan sponsors and/or Applicants are required to comply with all applicable requirements of the regulations in Part 423 of 42 CFR.

#### **3.1 Applicant Experience, Contracts, Licensure and Financial Stability**

##### **3.1.1 Management and Operations**

**A. Complete the table below:**

<b>APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:</b>	<b>YES</b>	<b>NO</b>	<b>Requesting Waiver? Yes or No</b>
1. Applicant is applying to operate as a cost plan sponsor.			
2. Applicant is a non-governmental legal entity that agrees to abide by the terms of a Medicare Prescription Drug Plan contract with CMS.			

**B. Describe below your staffing plan for the operation of your Part D benefit plan(s). In particular, discuss the number of staff that will be assigned to the following activities:**

- Financial
- Marketing
- Furnishing of Prescription Drug Services
- Quality Assurance
- Fraud and Abuse
- Medication Therapy Management
- Drug Utilization Management
- Claims Processing

**C. Complete the form below(s) to identify each of the entities with which you subcontract to serve the functions identified in Subsection 3.1.2 A. If more than one subcontractor has been engaged to meet these functions, identify each of the subcontractors within the relevant requirement column. Copy and paste the form, if you need additional space:**

<b>IDENTIFY YOUR SUBCONTRACTOR BY PROVIDING THE FOLLOWING INFORMATION</b>	
Full Legal Organization's Name of Subcontractor:	Function(s) Contracted for:
Full Address of Subcontractor's Headquarters ( <i>Street, City, State, Zip</i> ):	
Name of Chief Operating Officer:	
Name of Chief Financial Officer:	
Type of Ownership:	
<input type="checkbox"/> Sole Proprietorship <input type="checkbox"/> Partnership <input type="checkbox"/> Publicly-Traded Corporation <input type="checkbox"/> Privately- Held Corporation <input type="checkbox"/> Other (list type) _____	
Name of Subcontractor's Parent Organization, if any:	
State in Which Your Subcontractor is Incorporated or Otherwise Organized to do Business:	
Federal Taxpayer Identification Number:	
<b>PROVIDE INDIVIDUAL WHO WILL SIGN THE MEDICARE CONTRACT WITH THE PART D APPLICANT. THIS PERSON MUST BE AUTHORIZED TO ACT FOR THE SUBCONTRACTOR ENTITY:</b>	
Name of Individual:	Title:

**D. Provide as attachments (as instructed in Section 2.4) copies of executed contracts with each subcontractor identified in the above tables (3.1.1 C) that:**

1. Clearly identify the parties to the contract (or letter of agreement);
2. Describe the functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant;
3. Contain language clearly indicating that the subcontractor has agreed to participate in your Medicare Prescription Drug Benefit program (except for a network pharmacy if the existing contract would allow participation in this program), and flow-down clauses requiring their activities be consistent and comply with the Applicant's contractual obligations as a Part D sponsor;
4. Contain language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program;
5. Describe the payment the subcontractor will receive for performance under the contract, if applicable;
6. Are for a term of at least the first year of the program. (Please note that first year contracts between the Applicant and an entity performing Part D enrollment functions on behalf of the Applicant should have a start date no later than November 15, 2005, the first date of the first annual election period for Part D enrollments to be effective January 1, 2006. Future year terms are January 1 to December 31);
7. Are signed by a representative of each party with legal authority to bind the entity;
8. Contain language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions;
9. Contain language obligating the subcontractor to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for this program at 42 CFR §423.136;

10. Contain language ensuring that the subcontractor will make their books and other records available in accordance with 42 CFR 423.505 (i)(2). Generally stated these regulations give HHS, the Comptroller General, or their designees the right to inspect, evaluate and audit books and other records and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later.
11. Contain language that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Part D sponsor;
12. Contain language that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the subcontractor, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the subcontractor has not performed satisfactorily. The subcontract may include remedies in lieu of revocation to address this requirement;
13. Contain language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the subcontractor on an ongoing basis; and
14. If the subcontractor will establish the pharmacy network or select pharmacies to be included in the network, contain language that the Part D sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy.

Note: While CMS is only requesting certain contracts, elements 2, 8, 10, 11, 12, and 13 of section 3.1.1 D are required in all the Applicants contracts necessary to provide the Part D benefit.

**E. Provide as an attachment the signed certification in Appendix VI. The certification allows the Applicant to verify the subcontracts submitted under 3.1.1D meet all of the requirements identified in 3.1.1D.**

**F. Provide electronic lists of the subcontract citations demonstrating that the requirements of Section 3.1.1D are included in the subcontracts. Submit these data by creating a spreadsheet in Microsoft Excel that mimics Appendix VII. Provide this attachment on a CD as instructed in Section 2.4.**

### **3.1.2 Experience and Capabilities**

**A. Complete the table below:**

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	YES	NO	Requesting Waiver? Yes or No
1. Applicant and/or one of its subcontractors currently operates a pharmacy benefit program that performs adjudication and processing of pharmacy claims at the point of sale.			
2. Applicant and/or one of its subcontractors currently operates a pharmacy benefit program that performs negotiation with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs.			
3. Applicant and/or one of its subcontractors currently operates a pharmacy benefit program that performs administration and tracking of enrollees' drug benefits in real time.			
4. Applicant and/or one of its subcontractors currently operates a pharmacy benefit program that performs coordination with other drug benefit programs, including, for example, Medicaid, state pharmaceutical assistance programs, Medigap, or other insurance.			

5. Applicant and/or one of its subcontractors currently develops and maintains a pharmacy network.			
6. Applicant and/or one of its subcontractors currently operates a pharmacy benefit program that operates an enrollee grievance and appeals process.			
7. Applicant and/or one of its subcontractors currently operates a pharmacy benefit program that performs customer service functionality, that includes serving seniors and persons with a disability.			

**B. As part of the discussion of the experience described immediately above, please indicate the 2004 business volumes your organization has generated in operating your benefit by completing the table below:**

<b>PHARMACY-RELATED ENTITIES</b> <b>INSURED PHARMACY BENEFITS <sup>(#1)</sup></b>		
Metric for Calendar Year 2004	Retail	Mail
Covered Lives <sup>(#2)</sup>		
Senior Lives (if available)		
Claims Processed or Total Utilization	Check: <input type="checkbox"/> Claims Processed, or <input type="checkbox"/> Total Utilization	Check: <input type="checkbox"/> Claims Processed, or <input type="checkbox"/> Total Utilization
Drug Spending Managed		
<b>IF THE ENTITY UNDERWENT SIGNIFICANT CHANGE IN 2004, OR IT EXPECTS IN 2005 TO HAVE SUBSTANTIALLY DIFFERENT BUSINESS VOLUMES, PLEASE COMMENT BELOW AND PROVIDE 2005 PROJECTED VOLUMES IN ADDITION TO YOUR BUSINESS VOLUMES FOR 2004:</b>		

#1 Exclusive of any prescription drug discount card programs

#2 a) Covered lives are discrete individuals for whom there is verifiable information / documentation that, on audit, would demonstrate their enrollment in the insured benefits program through either hard copy signed agreements, payment of insurance premiums, or some comparable verification. Covered lives are not demonstrated or accounted for by hits on a Web site or number of prescriptions filled or for which a claim was processed. Nor are covered lives demonstrated by counting signed agreements and multiplying by an average family size (if a **family** premium was paid, the "family" is 2 people; unless the organization can document additional family members are included).

b) To calculate covered lives, use most recent data. Applicants should pick a point in time within the previous 12 months and provide the number of unique lives. Please specify month for point in time used.

### **3.1.3 Business Integrity**

**A. Complete the table below:**

APPLICANT MUST ATTEST 'YES' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN..	Yes	No	Requesting Waiver? Yes or No
Applicant and its affiliated companies, subsidiaries or subcontractors, subcontractor staff, any member of its board of directors, and any key management or executive staff agree that they are bound by 45 CFR Part 76 and attest that they are not excluded by the Department of Health and Human Services Office of the Inspector General or by the General Services Administration.			

**B. List any past or pending, if known, investigations, legal actions, or matters subject to arbitration brought involving the Applicant (and Applicant's parent firm if applicable) and its subcontractors, including any key management or executive staff, or any major shareholders (5% or more), by a government agency (state or federal) over the past three years on matters relating to payments from governmental entities, both federal and state, for healthcare and/or prescription drug services. Provide a brief explanation of each action, including the following:**

- 1) Legal names of the parties;
- 2) Circumstances;
- 3) Status (pending or closed);
- 4) If closed, provide the details concerning resolution and any monetary payments;
- and
- 5) Settlement agreements or corporate integrity agreements.

### **3.2 Benefit Design**

#### **3.2.1 Pharmacy and Therapeutics (P&T) Committee**

**A. Complete the form below:**

<b>INDICATE IF THE APPLICANT ANTICIPATES SUBMITTING A FORMULARY</b>
<i>Note: CMS is using this information to understand how many formularies it may need to review beginning April 18, 2005.</i>
Check Yes or No <input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, indicate how many formularies you anticipate to submit:
If no, indicate if all drugs will have the same cost-sharing? <input type="checkbox"/> Yes <input type="checkbox"/> No

**B. Complete the table below:**

APPLICANT MUST ATTEST 'YES' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN..	YES	NO
Applicant will submit a formulary, if answered "No" to "Indicate if all drugs will have the same cost-sharing" in 3.2.1 B above.		

**C. Complete the form below:**

PROVIDE THE NAMES OF THE MEMBERS OF YOUR ORGANIZATION'S P&T COMMITTEE. INDICATE WHICH MEMBERS ARE PRACTICING PHYSICIANS OR PRACTICING PHARMACISTS. FURTHER, INDICATE WHICH MEMBERS ARE, EXPERTS IN THE CARE OF THE ELDERLY OR DISABLED, AND FREE OF ANY CONFLICT OF INTEREST WITH YOUR ORGANIZATION AND PHARMACEUTICAL MANUFACTURERS. (APPLICANTS SHOULD MARK THE INFORMATION AS PROPRIETARY.) ADD ADDITIONAL ROWS AS NECESSARY

Full Name of Member	Practice/Expertise <i>Mark an 'X' in Appropriate Column</i>			Free of Any Conflict of Interest <i>Type Yes or No</i>	
	Practicing Physician	Practicing Pharmacist	Elderly/Disabled Expert	With Your Organization?	With Pharmaceutical Manufacturers?

**D. Complete the table below:**

REPLY 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN. IF APPLICANT INDICATED IN 3.1.2.A, 'YES,' THAT APPLICANT IS PROVIDING A FORMULARY THEN THE APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. IF APPLICANT INDICATED 'NO' IN 3.1.2 A, THAT IT IS NOT PROVIDING A FORMULARY AND REPLIES NO TO ANY OF THE ATTESTATIONS BELOW, THIS WILL NOT DISQUALIFY THE APPLICANT FROM A CONTRACT.	YES	NO	Requesting Waiver? Yes or No
1. Applicant will develop and use a P&T committee to develop and review the formulary and to ensure that the formulary is appropriately revised to adapt to both the number and types of drugs on the market.  <i>Note: While the P&amp;T committee may be involved in providing recommendations regarding the placement of a particular Part D drug on a formulary cost-sharing tier, the ultimate decision maker on such formulary design issues is the Part D plan, and that decision weighs both clinical and non-clinical factors.</i>			
2. Applicant's P&T committee will first look at medications that are clinically effective. When two or more drugs have the same therapeutic advantages in terms of safety and efficacy, the committee may review economic factors that achieve appropriate, safe, and cost-effective drug therapy.			
3. Applicant will assure that the P&T committee uses appropriate scientific and economic considerations to consider utilization management activities that affect access to drugs, such as access to non-formulary drugs, prior authorization, step therapy, generic substitution, and therapeutic interchange protocols.			
4. Applicant will adhere to P&T guidelines that will, from time to time, be promulgated with regard to such subject areas as membership, conflict of interest, meeting schedule, meeting minutes, therapeutic classes, drug review and inclusion, formulary management, utilization management and review, formulary exceptions, and educational programs for providers.			
5. Applicant's P&T committee will make reasonable efforts to review within 90 days, and will make a decision on each new chemical entity and new FDA clinical indicators within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met.			
6. Applicant's P&T committee will approve inclusion or exclusion of the therapeutic classes in the formulary on an annual basis.			
7. The majority of the membership of the Applicant's P&T committee shall be practicing physicians and/or practicing pharmacists.			
8. The membership of the Applicant's P&T committee will include at least one			

practicing physician and at least one practicing pharmacist who are free of conflict with respect to the Applicant organization and pharmaceutical manufacturers.			
9. The membership of the Applicant's P&T committee will include at least one practicing physician and at least one practicing pharmacist who are experts in the care of the elderly or disabled persons.			
10. Applicant's P&T committee will recommend protocols and procedures for the timely use of and access to both formulary and non-formulary drug products.			

### **3.2.2 Utilization Management Standards**

#### **A. Complete the table below:**

<b>APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.</b>	<b>YES</b>	<b>NO</b>	<b>Requesting Waiver? Yes or No</b>
1. Applicant maintains policies and procedures to prevent over-utilization and under-utilization of prescribed medications, including but not limited to the following elements: <ul style="list-style-type: none"> <li>• Compliance programs designed to improve adherence/persistence with appropriate medication regimens</li> <li>• Monitoring procedures to discourage over-utilization through multiple prescribers or multiple pharmacies</li> <li>• Quantity versus time edits</li> <li>• Early refill edits</li> </ul>			
2. Applicant maintains methods to ensure cost-effective drug utilization management. Examples of these tools include, but are not limited to: <ul style="list-style-type: none"> <li>• Step therapy</li> <li>• Prior authorization</li> <li>• Tiered cost-sharing</li> </ul>			
3. Applicant makes enrollees aware of utilization management program requirements through information and outreach materials.			
4. Applicant develops incentives to reduce costs when medically appropriate such as, but not limited to encouragement of generic utilization.			
5. Applicant will report to CMS data for UM standards in the manner prescribed by CMS. (See Section 3.11 Reporting Requirements)			

### **3.2.3 Quality Assurance and Patient Safety**

**A. Complete the table below:**

<b>APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.</b>	<b>YES</b>	<b>NO</b>	<b>Requesting Waiver? Yes or No</b>
1. Applicant establishes a quality assurance program that includes measures and reporting systems such as, but not limited to: <ul style="list-style-type: none"> <li>Reducing medication errors</li> <li>Reducing adverse drug interactions</li> </ul>			
2. Applicant performs drug utilization review at a minimum of what is specified in the regulation 42CFR 423.153 (c) (2) and (3).			
3. Applicant will ensure patient counseling is offered to enrollees, when appropriate.			
4. Applicant develops and implements internal medication error identification and reduction systems.			
5. Applicant ensures network pharmacies implement a method for maintaining up-to-date enrollee information such as, but not limited to: <ul style="list-style-type: none"> <li>Enrollee demographic information</li> <li>Enrollee allergy information (drug and food)</li> </ul>			
6. Applicant will report to CMS data for QA standards in the manner prescribed by CMS. (See Section 3.11 Reporting Requirements)			
7. Applicant will establish appropriate transition policies and procedures for beneficiaries on drug regimens that are not on the plan's Part D formulary. These policies and procedures must address all the elements specified in formulary transition guidance to be provided by CMS in early March.			
8. The Applicant agrees to submit to CMS on April 18, 2005 a description of the organization's approach to transitioning beneficiaries on drug regimens that are not on the plan's Part D formulary (see note below).			
9. Applicant will establish appropriate policies and procedures for addressing the immediate needs of enrollees who are LTC <b>residents in situations where there is a disparity between the Part D requirements and the Medicare conditions of participation (COPs) for LTC facilities.</b>			
10. <b>The Applicant agrees to submit to CMS on April 18, 2005 a description of the organization's approach to address the immediate needs of enrollees who are LTC residents in situations where there is a disparity between the Part D requirements and the Medicare conditions of participation for LTC facilities. (see note below)</b>			

**NOTE:** The answer to Item #8 and #10 will be collected in HPMS and should be submitted with the Applicant's formulary under the exception /notes transition word file provided in HPMS. The format will be delineated in HPMS user instructions that will be released in March.

### 3.2.4 Medication Therapy Management

A. Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	YES	NO	Requesting Waiver? Yes or No
1. Applicant will develop and implement a Medication Therapy Management (MTM) Program designed to : <ul style="list-style-type: none"> <li>• Ensure optimum therapeutic outcomes for targeted beneficiaries through improved medication use</li> <li>• For targeted beneficiaries, reduce the risk of adverse events, including adverse drug interactions</li> </ul>			
2. Applicant will develop the MTM program in cooperation with licensed and practicing pharmacists and physicians.			
3. Applicant will target beneficiaries for enrollment in the MTM program based on using all three of the following criteria: <ul style="list-style-type: none"> <li>• Beneficiary must have multiple chronic diseases, such as diabetes, asthma, congestive heart failure, hyperlipidemia, and hypertension (list to be determined by plan);</li> <li>• Beneficiary must be taking multiple covered Part D medications (specifics to be determined by plan); and</li> <li>• Beneficiary must be identified as likely to incur annual costs for covered part D drugs that exceed \$4,000.00</li> </ul>			
4. Applicant will establish appropriate policies and procedures for their MTM program, including, but not limited to, services, payments and criteria used for identifying beneficiaries eligible for the MTM program.			
5. The Applicant agrees to submit to CMS on April 18, 2005 a description of their MTM program including, but not limited to, policies, procedures, services, payments and criteria provided in Item #3 above used for identifying beneficiaries eligible for the MTM program.			
6. Applicant will coordinate the MTM program with the Medicare chronic care improvement program (CCIP) under section 1807 of the Social Security Act.			
7. Applicant will provide drug claims data to Chronic Care Improvement Programs (CCIP) for those beneficiaries that are enrolled in CCIPs in a manner specified by CMS.			
8. Applicant will report to CMS specified data on MTM programs in the manner prescribed by CMS. (See Section 3.11 Reporting Requirements)			
9. Applicant will establish an appropriate policy on how they will set MTM fees to pharmacists or others providing MTM services for covered Part D drugs. The policy will explain how the Applicant's fee or payment structure takes into account the resources used and the time required for by those providing MTM services.			
10. The Applicant agrees to submit to CMS on April 18, 2005 a description on how they will set MTM fees to pharmacists or others providing MTM services for covered Part D drugs. The policy will explain how the Applicant's fee or payment structure takes into account the resources used and the time required for by those providing MTM services.			

- **NOTE:** In providing responses to items 5 and 10 above follow these directions: The responses must be submitted to CMS by 5p.m. EST on April 18, 2005. The responses should be submitted to CMS by email in a word document **and** courier. The emailed response should be sent to [drugbenefitimpl@cms.hhs.gov](mailto:drugbenefitimpl@cms.hhs.gov) and the

subject line must read Benefit Design Responses. Please include your contract number in the file name as well as in the cover page. The cover page should also specify that the responses are amendments to the March 23, 2005 application that are due on April 18, 2005. The cover page must be signed by an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to enter into a Part D contract with CMS. Clearly identify the element—3.2.4A5 or 3.2.4A10—in your response. The responses should be combined with additional responses required in Section 3.2.3. The responses must also be sent by courier to:

Centers for Medicare & Medicaid Services (CMS)  
 Marietta Mack  
 Mail Stop S1-05-06/Location S2-04-05  
 Attn: Benefit Design Responses  
 7500 Security Boulevard  
 Baltimore, Maryland 21244-1850

### **3.2.5 Electronic Prescription Program**

**A. Complete the table below:**

APPLICANT MUST ATTEST 'YES' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	YES	NO	Requesting Waiver? Yes or No
1. Once electronic prescribing standards are published and in effect, the Applicant agrees to have an electronic prescription program that supports electronic prescribing with pharmacies as well as physicians.			

### **3.3 Pharmacy Access**

**A. Complete the table below:**

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN..	YES	NO	Requesting Waiver? Yes or No
1. Applicant agrees to permit in their plan networks, any pharmacy that is willing to accept and meets the plans' standard terms and conditions. However, terms and conditions may vary, particularly with respect to payment terms to accommodate geographical areas (e.g. rural pharmacies) or different types of pharmacies (e.g. mail order and retail), provided that all similarly-situated pharmacies are offered the same standard terms and conditions.			
2. Applicant agrees not to require a pharmacy to accept insurance risk as a condition of participation in the Cost Plan's optional supplemental Part D pharmacy network.			

3. Applicant's network pharmacy contracts contain provisions governing submitting claims to a real-time claims adjudication system.			
4. Applicant's network pharmacy contracts contain provisions governing providing access to negotiated prices.			
5. Applicant's network pharmacy contracts contain provisions regarding charging/ applying the correct cost-sharing amount, including that which applies to individuals qualifying for the low-income subsidy.			
6. Applicant's network pharmacy contracts contain provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price.			

Note: While CMS realizes that contracts with Indian Health Services, Indian Tribes and Tribal organizations and Urban Indian Organization (I/T/U), Federally Qualified Health Centers (FQHC) and Rural Health Centers (RHC) may be counted for purposes of meeting the pharmacy access standards, it should be noted that contracts with these pharmacies may not be used as a substitution for inclusion in plan networks of retail pharmacies.

**B. Provide as an attachment the unsigned standard terms and conditions offered in the contract (or addenda to the contract) for each of the following types of pharmacies: Retail, Mail Order, Home Infusion, I/T/U, and Long-Term Care. The mail order contract is only necessary if the plan is offering mail order. If there are several different types of standard terms and conditions for the same type of pharmacy, please provide all versions. For example, if different terms for retail pharmacies apply depending upon geographic location, all standard terms must be provided.**

- Contracts (or addenda to contracts) must contain all of the required provisions described in 3.1.1D for contracts or letters of agreement with the Applicant's subcontractors except for the following numbers 1, 3, 5, 6, 7, and 14.
- No signature pages need be submitted at this time, but each Applicant must make a complete file of such pages available for inspection upon CMS' request.

**C. Provide electronic lists of the Pharmacy Access Contract Citations demonstrating that the applicable requirements in 3.1.1D, 3.3A, 3.3.5 and 3.3.6B are included in such contracts. Submit this data by creating a spreadsheet in Microsoft Excel that mimics Appendix VIII. Provide this attachment on a CD as instructed in Section 2.4. This information must be clearly labeled to indicate to which party of the joint enterprise the information pertains.**

### **3.3.1 Retail Pharmacy**

If your organization will provide enrollees with access to covered Part D drugs through pharmacies owned and operated by your organization under 42 CFR §423.120 (a)(3)(i) these pharmacies may be included in determining pharmacy network access for your Cost Plan population. Pharmacies owned and operated by your organization may be included in your pharmacy network to demonstrate equivalent access in items A, B, C below.

**A. Complete the table below:**

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN..	YES	NO	Requesting Waiver? Yes or No
1. Applicant agrees to meet the CMS Standards for Convenient Access [§423.120 (a)(1) and (2)] as early as March 23, 2005 but no later than July 15, 2005 (See Appendix IV).			
2. Applicant agrees that if these pharmacy access standards are not fully met by March 23, 2005, that Applicant will resubmit the analysis in Section 3.4.1 (A) on August 1, 2005.			
3. Applicant agrees to permit enrollees to receive benefits which may include a 90-day supply of covered Part D drugs at any of its network pharmacies that are retail pharmacies instead of at a network mail-order pharmacy.			

Note: Concerning the rural access standard, there may be several States for which the standard will be impossible or impracticable to meet given the lack of infrastructure. CMS will identify these States and make an exception to meeting this requirement based on analysis of the number of retail pharmacies in the State, the State's Medicare population and the access ratios across plans that include these States in their service area.

**B. Using Geographic Information Systems (GIS) or similar software, demonstrate in the March 23, 2005 application, the applicant's pharmacy access ratios for their intended service area using only the pharmacies for which contracts are executed for the Part D benefit. Please note that:**

- As defined in 42 CFR 423.100:
  - urban areas are five-digit ZIP Codes in which the population density is greater than 3,000 persons per square mile;
  - suburban areas are five-digit ZIP Codes in which the population density is equal to or greater than 1,000 persons per square mile and less than or equal to 3,000 persons per square mile; and
  - rural areas are five-digit ZIP Codes in which the population density is less than 1,000 persons per square mile.

Note: If the convenient access standards are not satisfied on the March 23, 2005 application, then these analyses must also be submitted to CMS on August 1, 2005.

- The demonstration of pharmacy access must be based on a computation using of beneficiary counts by Zip Code provided by CMS at <http://www.cms.hhs.gov/pdps> (File Name: "MCareEnrbyZip062004.zip" ). Due to periodic changes in ZIP codes, CMS recognizes that some ZIP codes in the data provided by CMS may not "map" to current ZIP code listings for your service area. These ZIP codes may be excluded from your summary analyses.
- Maps and tables must be generated for the Applicant's entire service area using the locations for the pharmacy network under contract for the Part D benefits and the standard beneficiary file provided to bidders at <http://www.cms.hhs.gov/pdps>. This network analysis may include only retail (non-mail-order) pharmacies, I/T/U pharmacies, and pharmacies operated by a FQHC or RHC as provided in Section 423.120 (a) (1) and (a) (2). Applicants are responsible for insuring the urban,

suburban, and rural definitions used in their analyses conform with the definitions for these areas as provided in 42 CFR 423.100. Most network access analysis programs default to classifications consistent with the regulatory requirements. Upon request by an applicant, CMS will provide urban, suburban, and rural classifications by beneficiary Zip Code based on the relation of CMS beneficiary ZIP codes to ZIP code Tabulation Areas (ZCTAs). The population densities used in this file are based on the U.S. Census Bureau's ZCTA Gazetteer file.<sup>1</sup> Use of this more detailed file by applicants is not required. This file is available to applicant organizations that require further detail for mapping classification purposes.<sup>2</sup>

- Maps and tables generated by the mapping software must include aggregate urban, suburban, and rural ratios for the entire service area to be served by the PDP sponsor, as well as urban, suburban, and rural ratios for each region, state, county, and Zip Code included under the program.

**C. Provide an electronic list of all contracted retail pharmacy outlets included in the analysis. Submit this data by creating a spreadsheet in Microsoft Excel that mimics the table below. Provide this attachment on a CD as instructed in Section 2.4. Submit this list to CMS with the March 23, 2005 application and again on August 1, 2005 if there are changes.**

Full Name of Pharmacy	Full Address				Pharmacy Telephone Number	Contact	NABP Number	Pharmacy Type Mark Preferred (P) or Non-Preferred (N)
	Street	City	State	Zip				

### **3.3.2 Out of Network Pharmacy**

**A. Complete the table below:**

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN..	YES	NO	Requesting Waiver? Yes or No
1. Applicant agrees to assure that enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when an enrollee cannot reasonably be expected to obtain such drugs at a network pharmacy and provided such enrollees do not access Part D drugs at an out-of-network pharmacy (or a physician's office) on a routine basis.			
2. Applicant agrees to ensure that enrollees have adequate access to covered Part D drugs dispensed at physician offices for covered Part D drugs that are appropriately dispensed and administered in physician offices (e.g. Part D-covered vaccines).			
3. Applicant agrees to abide by Section 423.124(b) relating to the financial responsibility for out-of-network access to covered Part D drugs and may require its Part D enrollees accessing covered Part D drugs to assume financial responsibility for any differential between the out-of-network pharmacy's usual and customary price and the Part D sponsor plan allowance, consistent with the requirements of § 423.104(d)(2)(i)(B) and § 423.104(e).			
4. Applicant agrees to develop policies and procedures governing reasonable rules			

<sup>1</sup> See <http://www.census.gov/geo/www/gazetteer/places2k.html>

<sup>2</sup> Requests for this file should be submitted to [dhodges@cms.hhs.gov](mailto:dhodges@cms.hhs.gov) with the subject line: **ZIP Classification File Request**

<p>to appropriately limit out-of-network access and to include at least the following: Beneficiary is guaranteed out-of-network access when:</p> <ul style="list-style-type: none"> <li>• Traveling outside his or her plan's service area and runs out of or loses his or her covered Part D drugs or becomes ill and needs a covered Part D drug, and cannot access a network pharmacy;</li> <li>• Not able to obtain a covered Part D drug in a timely manner within his or her service area because, for example, there is no network pharmacy within a reasonable driving distance that provides 24/7 service;</li> <li>• Filling a prescription for a covered Part D drug and that particular drug (for example, an orphan drug or other specialty pharmaceutical) is not regularly stocked at an accessible network retail or mail-order pharmacy;</li> <li>• Provided covered Part D drugs dispensed by an out-of-network institution-based pharmacy while a patient is in an emergency department, provider-based clinic, outpatient surgery, or other outpatient setting.</li> </ul>			
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### **3.3.3 Mail Order Pharmacy**

**A. Complete the table below:**

APPLICANTS <u>MAY</u> OFFER A MAIL ORDER OPTION <u>IN ADDITION</u> TO THEIR CONTRACTED OPTIONAL SUPPLEMENTAL PART D PHARMACY NETWORK BUT MAIL ORDER PHARMACIES DO NOT COUNT IN MEETING NETWORK ADEQUACY STANDARDS. INDICATE 'YES' OR 'NO' WHETHER SUCH MAIL ORDER PHARMACY IS OFFERED.	YES	NO	Requesting Waiver? Yes or No
1. Applicant will offer mail order pharmacy as part of its Part D plans.			

**B. Provide an electronic list, with the March 23, 2005 application, of all Applicant- owned and/or contracted mail order pharmacies to provide Part D benefits – only if your optional supplemental Part D benefit will include them. *Submit this data by creating a spreadsheet in Microsoft Excel that mimics the table below. Provide this attachment on a CD as instructed in Section 2.4. Provide an updated list on August 1, 2005 if there are changes.***

Full Name of Pharmacy	Full Address				Pharmacy Telephone Number	Contact	NABP Number	Pharmacy Type Mark Preferred (P) or Non-Preferred (N)
	Street	City	State	Zip				

### **3.3.4 Home Infusion Pharmacy**

**A. Complete the table below:**

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN..	YES	NO	Requesting Waiver? Yes or No
1. Applicant agrees to provide adequate access to home infusion pharmacies.			
2. Applicant provides the analysis required in "B" below with the March 23 application, or Applicant agrees to provide it no later than August 1, 2005.			
3. Applicant agrees that its network contracts will address Part D drugs delivered in			

the home setting through home infusion therapy pharmacies.			
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**B. Provide a map and table generated by mapping software of the dispersion of the Applicant's contracted home infusion pharmacies, as well as the ratios of beneficiaries to these pharmacies for the entire service area and for each region, state and county. Use the standard beneficiary file provided to bidders at <http://www.cms.hhs.gov/pdps/> (Filename: "MCareEnrbyZIP062004.zip"). Based on the findings in this map and table, describe how the home infusion pharmacies in the Applicant's network adequately provides the Part D benefit to the beneficiaries that the Applicant intends to enroll throughout its proposed service area. Submit this information to CMS with the March 23, 2005 application or on August 1, 2005. Note: Documentation for Home Infusion Access (3.4.4 B) and Home Infusion Pharmacy List (3.4.4 C) must be submitted at the same time.**

**C. Provide an electronic list of all contracted Home Infusion Pharmacies to provide Part D benefits. Submit this data by creating a spreadsheet in Microsoft Excel that mimics the table below. Provide this attachment on a CD as instructed in Section 2.4. Submit this list when the response to 3.4.4 B is provided to CMS.**

Full Name of Pharmacy	Full Address				Pharmacy Telephone Number	Contact	NABP Number	Pharmacy Type Mark Preferred (P) or Non-Preferred (N)
	Street	City	State	Zip				

### **3.3.5 Long -Term Care (LTC) Pharmacy**

**A. Complete the table below:**

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN..	YES	NO	Requesting Waiver? Yes or No
1. Applicant agrees to offer standard contracting terms and conditions to all long-term care pharmacies in its service area. These terms and conditions must include all the performance and service criteria for long-term care pharmacies that CMS will specify in a future Long-Term Care Guidance document			
2. Applicant agrees to recognize the CMS special election period (SEP) or open enrollment period for institutionalized individuals (OEPI) for Part D drug plan enrollment and disenrollment for beneficiaries entering, living in, or leaving a long-term care facility.			
3. Applicant agrees that if contracts with long-term care pharmacies are not fully executed by March 23, 2005, that Applicant will need to resubmit the analysis requested below on August 1, 2005.			
4. Applicant agrees that it will contract with a sufficient number of LTC pharmacies to provide all of the plan's institutionalized enrollees convenient access to their Part D benefit.			
5. Applicant provides the analysis required in "C" below with the March 23, 2005 application, or Applicant agrees to provide it on August 1, 2005.			

**Note:** CMS will release Long-Term Care Guidance in early March, 2005. This document will contain a list of Performance and Service Criteria, as referenced in item #1 of the above table. Applicants will be required to incorporate, at a minimum, those criteria in any LTC pharmacy network contract.

**B. Provide a work plan with the March 23, 2005 application outlining the Applicant's strategy for completing contracting with long-term care pharmacies in proposed service area by July 15, 2005 and in time to submit access information by August 1, 2005. Work plan should include (but is not limited to) activities with and target dates for the following major milestones: identification of LTC pharmacies, conducting outreach, contract offering, arrangements for discussion/negotiation, anticipated contract closure, tracking progress and assessing progress to modify approach as necessary.**

**C. On August 1, 2005 provide an electronic list of all contracted Long-Term Care Pharmacies to provide Part D benefits. *Submit this data by creating a spreadsheet in Microsoft Excel that mimics the table below. Provide this attachment on a CD as instructed in Section 2.4.***

Full Name of Pharmacy	Full Address				Pharmacy Telephone Number	Contact	NABP Number	Pharmacy Type Mark Preferred (P) or Non-Preferred (N)
	Street	City	State	Zip				

**D. Describe how the long-term care pharmacies in the Applicant's network represents a sufficient number of long-term care pharmacies to provide all of the plan's institutionalized enrollees with convenient access to their Part D benefit..**

### **3.3.6 Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacy**

**A. Complete the table below:**

APPLICANT MUST ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN TO BE APPROVED FOR A COST PLAN CONTRACT.:	YES	NO	Requesting Waiver? Yes or No
1. Using the list of I/T/U pharmacies provided at <a href="http://www.cms.hhs.gov/pdps">http://www.cms.hhs.gov/pdps</a> or <a href="http://www.cms.hhs.gov/aian/">http://www.cms.hhs.gov/aian/</a> , indicate whether your service area includes at least one I/T/U pharmacy.			

**B. Complete the table below:**

NOT ALL PART D REGIONS HAVE I/T/U PHARMACIES. IF THE APPLICANT'S SERVICE AREA COVERS <u>ANY</u> REGION THAT INCLUDES I/T/U PHARMACIES, THEN THE APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. IF <u>ALL</u> OF THE APPLICANT'S SERVICE AREA <u>DOES NOT</u> INCLUDE I/T/U PHARMACIES, THEN THE APPLICANT MAY ANSWER 'NO' AND STILL BE APPROVED FOR A COST PLAN CONTRACT SINCE THESE REQUIREMENTS DO NOT APPLY. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO	Requesting Waiver? Yes or No
1. Applicant agrees to offer standard terms and conditions that conform to the model contract addenda provided by CMS to all I/T/U pharmacies in its service area.			

These model addenda are located at: <a href="http://www.cms.hhs.gov/pdps/">http://www.cms.hhs.gov/pdps/</a> and <a href="http://www.cms.hhs.gov/aian/">http://www.cms.hhs.gov/aian/</a> . The model contract addenda account for differences in the operations of I/T/U pharmacies and retail pharmacies.			
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Note: Information for Part D Sponsors on Contracting with Indian Health Care Providers is located at: <http://www.cms.hhs.gov/pdps/> and <http://www.cms.hhs.gov/aian/>.

**C. Provide below a work plan with the March 23, 2005 application, outlining the Applicant's strategy for completing contracting with I/T/U pharmacies in proposed service area by July 15, 2005 and in time to submit access information on August 1, 2005. The work plan should include (but is not limited to) activities associated with and target dates for the following major milestones.: identification of I/T/U pharmacies, conducting outreach, contract offering, arrangements for discussion/negotiation, anticipated contract closure, tracking progress and assessing progress to modify approach as necessary. Also included in this work plan should be a period not to exceed 45 days for an I/T/U pharmacy to enter into a contract with the plan once the contract has been offered to the pharmacy.**

**D. On August 1, 2005 provide an electronic list (by State) for each I/T/U Pharmacy. *Submit this data by creating a spreadsheet in Microsoft Excel that mimics the table below. Provide this attachment on a CD as instructed in Section 2.4.***

Full Name of Pharmacy	Full Address				Phone Number	Contact	NABP or ASEP No.	Pharmacy Type Mark Preferred (P) or Non-Preferred (N)	Status of Contract Mark with an "X"			
	Street	City	State	Zip					Date of Offer	Accepted	Declined	Under Negotiation

### **3.4 Enrollment and Eligibility**

**A. Complete the table below:**

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN..	YES	NO	Requesting Waiver? Yes or No
1. Applicant will permit the enrollment in the optional Part D Supplemental Benefit of all Medicare beneficiaries who are eligible for Part D and reside in the Cost Plan's service area during allowable enrollment periods according to CMS requirements to be issued in April 2005.			
2. Applicant will accept facilitated enrollment in the optional supplemental Part D benefit in accordance with procedures adopted by CMS for certain low-income beneficiaries who have failed to enroll in a Part D plan offering qualified prescription drug coverage.			
3. Applicant will not enroll in the optional supplemental Part D benefit any beneficiary who is already enrolled in a Part D plan who is in the Applicant's Cost Plan.			
4. Applicant will accept enrollments in the optional supplemental Part D benefit from beneficiaries beginning November 15, 2005.			
5. Applicant will collect and transmit data elements specified by CMS for the purposes of enrolling and disenrolling beneficiaries the optional supplemental			

Part D benefit in accordance with timeframes specified in CMS requirements to be issued in April 2005.			
6. Applicant will develop and operate a process for enrolling Medicare beneficiaries in the optional supplemental Part D benefit that includes: communicating with beneficiaries who are applying for enrollment in the optional supplemental Part D benefit within timeframes to be specified by CMS in April 2005; initiating appropriate follow up with beneficiaries who have incomplete enrollment applications; and making enrollments effective according to the effective date policy associated with the enrollment period in which the enrollment is received.			
7. Applicant will permit voluntary disenrollments in the optional supplemental Part D benefit.			
8. Applicant will accept and process disenrollment requests for the optional supplemental Part D benefit from beneficiaries, communicate these requests to CMS, and make the disenrollment effective according to the effective date policy associated with the enrollment period in which the disenrollment request is received.			
9. Applicant will develop policies and procedures for addressing beneficiary requests for a Special Enrollment Period and verifying a beneficiary's eligibility for a Special Enrollment Period.			
10. Applicant will notify beneficiaries in the event of a contract termination of the termination and alternatives for obtaining prescription drug coverage under Part D in accordance with Part 423 regulations.			
11. Applicant will develop and implement by November 15, 2005, policies and procedures (including appropriate notice and due process requirements) for optional involuntary disenrollment as permitted by CMS.			
12. Applicant will provide Part D identification card to enrollees by January 1, 2006, consistent with CMS requirements to be issued in April 2005.			

### **3.5 Exceptions, Appeals, and Grievances**

#### **A. Exceptions and Appeals - Complete the table below:**

<b>APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.</b>	<b>YES</b>	<b>NO</b>	<b>Requesting Waiver? Yes or No</b>
1. Applicant will adopt policies and procedures for beneficiary coverage determination, exceptions, and appeals consistent with 42 CFR §423 subpart M.			
2. Applicant will assure that it will comply with 423.578(a) and 423.578 (b) which require a Cost Plan sponsor to grant a tiering or off –formulary exception whenever it determines an exception is medically appropriate because the preferred drug (or on-formulary drug in the case of a formulary exception request): (a) would not be as effective for the enrollee as the requested drug; or (b) would have adverse effects for the enrollee, or (c) both.			
3. Applicant will make its enrollees aware of the coverage determination, exceptions, and appeals process through information provided in the Evidence of Coverage and outreach materials.			
4. Applicant will establish and maintain a process designed to track and address in a timely manner enrollees' exceptions requests, requests for coverage determination, re-determination, requests for reconsideration by the Independent Review Entity (IRE), and requests for review by the Administrative Law Judge (ALJ) received both orally and in writing, that includes, at a minimum: <ul style="list-style-type: none"> <li>• Date of receipt;</li> </ul>			

<ul style="list-style-type: none"> <li>• Date of any notification;</li> <li>• Disposition of request; and</li> <li>• Date of disposition</li> </ul>			
5. Applicant will make available to CMS upon CMS request , exception and appeals records.			

### **B. Grievances – Complete the table below**

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	YES	NO	Requesting Waiver? Yes or No
1. Applicant will establish and maintain a process designed to track and address enrollees' grievances and assures that they will adopt appropriate timelines, policies and procedures and train the relevant staff and subcontractors on such policies and procedures in accordance with 42CFR 423.564.			
2. Applicant will make enrollees aware of the grievance process through information and outreach materials.			
3. Applicant will accept grievances from enrollees at least by telephone and in writing (including facsimile)			
4. Applicant will maintain and provide upon request by CMS access to records on all grievances received both orally and in writing, that includes, at a minimum: <ul style="list-style-type: none"> <li>• Date of receipt of the grievance</li> <li>• Mode of receipt of grievance (i.e. fax, telephone, letter, etc.)</li> <li>• Person or entity that filed the grievance</li> <li>• Subject of the grievance</li> <li>• Final disposition of the grievance</li> <li>• Date the enrollee was notified of the disposition</li> </ul>			

Note: A grievance is any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of a Part D sponsor's operations, activities, or behavior, regardless of whether remedial action is requested.

Examples of subjects of a grievance include, but are not limited to:

- Timeliness, appropriateness, access to, and/or setting of services provided by the Part D sponsor
- Concerns about waiting times, demeanor of pharmacy or customer service staff
- A dispute concerning the timeliness of filling a prescription or the accuracy of filling the prescription.

### **3.6 Coordination of Benefits**

#### **A. Complete the table below:**

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN..	YES	NO	Requesting Waiver? Yes or No
1. Applicant develops and operates a system for collecting information from enrollees about enrollees' other health insurance, including whether such insurance covers outpatient prescription drugs.			

2. Applicant permits SPAPs and other third party payers to coordinate benefits as required by the regulations in Subpart J, Part 423, 42 CFR. For example, an SPAP might pay the premium for supplemental benefits on behalf of a beneficiary.			
3. Applicant will abide by the guidance of CMS regarding the Coordination of Benefit requirement to be released July 1, 2005.			
4. Applicant agrees to pay user fees as required under 423.6 and may be required in 423.464(c).			
5. Applicant agrees not to impose fees on SPAPs or other third-party insurers unrelated to the cost of coordination of benefits.			

### **3.7 Tracking Out-of Pocket Costs (TrOOP)**

**A. Complete the table below:**

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN..	YES	NO	Requesting Waiver? Yes or No
1. Applicant will track each enrollee's true out of pocket (TrOOP) costs reflecting the amount the enrollee has spent out-of-pocket during a program year on covered Part D drugs.			
2. Applicant will accept data concerning third party payers in a format to be specified by CMS no later than April 2005 for use in the Applicant's TrOOP calculation.			
3. Applicant will provide each enrollee with a report on their TrOOP status at least monthly.			
4. Applicant will provide enrollees daily access to their current TrOOP status through the organization's toll-free customer service phone number.			
5. In the event of disenrollment, Applicant agrees to provide TrOOP status of the beneficiary as of the effective date of the disenrollment.			

### **3.8 Marketing/Beneficiary Communications**

**A. Complete the table below:**

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	YES	NO	Requesting Waiver? Yes or No
1. Applicant will make available to beneficiaries only those marketing materials that comply with CMS' marketing guidelines and compiled with CMS approval procedures in accordance with CMS guidelines and regulations to be issued in April 2005.			
2. Annually and at the time of enrollment, the Applicant agrees to provide enrollees information about the following Part D benefit features, as described in the marketing guidelines:			

<ul style="list-style-type: none"> <li>• Enrollment Procedures;</li> <li>• Beneficiary Procedural Rights;</li> <li>• Potential for Contract Termination;</li> <li>• Benefits;</li> <li>• Types of Pharmacies in the Pharmacy Network;</li> <li>• Out-of-network Pharmacy Access;</li> <li>• Formulary;</li> <li>• Premiums;</li> <li>• Service Area;</li> <li>• Quality and Performance Indicators;</li> <li>• Utilization Management Procedures;</li> <li>• Frequency of Beneficiary Grievances and Appeals; and</li> <li>• Financial Condition of the Part D Sponsor</li> </ul> <p>The Applicant further agrees to provide general coverage information, utilization and grievance information to any beneficiary upon request.</p>			
<p>3. Applicant will maintain a toll-free customer service call center that is open during usual business hours and provides customer telephone service in compliance with standard business practices. This means that the Applicant must comply with at least the following:</p> <ul style="list-style-type: none"> <li>• Call center operates during normal business hours, but not less than Monday through Friday from 8:00 AM to 4:30 PM for those time zones in which the Applicant offers a Part D benefit;</li> <li>• Eighty percent of all incoming customer calls are answered within 30 seconds;</li> <li>• The abandonment rate of all incoming customer calls does not exceed 5 percent;</li> <li>• Call center provides thorough information about the Part D benefit plan, including co-payments, deductibles, and network pharmacies;</li> <li>• Call center features an explicit process for handling customer complaints; and</li> <li>• Call center shall provide service to non-English speaking and hearing impaired beneficiaries</li> </ul>			
<p>4. Applicant will operate an Internet Web site that a) provides all the information described in Item #2 of this table, b) describes the Applicant's PDPs' current formularies, and c) provides 60-days' notice to potential and current plan enrollees of the removal or change in the tier placement of any drug on the plan's formulary.</p>			
<p>5. Applicant will provide its plan enrollees, in a form understandable to enrollees and on at least a monthly basis for those months in which the enrollees use their Part D benefits, an explanation of benefits that states a) the item or service for which payment was made; b) notice of the enrollee's right to an itemized statement; c) a year-to-date statement of the total Part D benefits provided in relation to deductibles, coverage limits, and annual out-of-pocket thresholds; d) cumulative year-to-date total of incurred costs; and e) applicable formulary changes.</p>			

Note: While cost plan sponsors have to meet the Part D marketing guideline, the CMS review process will be integrated in the Part C Review required under 42 CFR 417.428.

### **3.9 Provider Communications**

**A. Complete the table below:**

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN..	YES	NO	Requesting Waiver? Yes or No
1. Applicant operates a toll-free call center to respond to inquiries from pharmacies and providers regarding the Applicant's Medicare prescription drug benefit. Inquiries will concern such operational areas as claims processing, benefit coverage, claims submission, and claims payment.			

### **3.10 Compliance Plan**

**A. Complete the table below:**

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN..	YES	NO	Requesting Waiver? Yes or No
1. Applicant will implement a compliance plan that consists of written policies, procedures, and standards of conduct articulating your organization's commitment to abide by all applicable Federal and State standards.			
2. Applicant will implement a compliance plan that designates a compliance officer and compliance committee accountable to senior management.			
3. Applicant will implement a compliance plan that includes effective training and education between the compliance officer and organization employees, contractors, agents and directors.			
4. Applicant will implement a compliance plan that includes effective lines of communication between the compliance officer and organization employees, contractors, agents, directors and members of the compliance committee.			
5. Applicant will implement a compliance plan that includes disciplinary standards that are well-publicized within the organization;			
6. Applicant will implement a compliance plan that includes procedures for internal monitoring and auditing.			
7. Applicant will implement a compliance plan that includes procedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the Applicant's contract as a Part D sponsor.			
8. Applicant will implement a compliance plan that includes a comprehensive plan to detect, correct, and prevent fraud, waste and abuse.			

Note: CMS recommends to Applicants that they include in their compliance plans provisions requiring the reporting of fraud and abuse to the appropriate government authority. Part D sponsors that self-report violations will continue to receive the benefits of voluntary self-reporting found in the False Claims Act and Federal sentencing guidelines.

Note: CMS acknowledges that prospective Part D sponsors may not have time to develop a satisfactory compliance plan prior to the due date for this application. Therefore, the Applicant must provide brief responses to the following elements as part of its application, which may reflect a finalized compliance plan or work in progress toward a final plan.

**B. Describe below the fraud and abuse section of your organization's compliance plan as it would apply to the operation of your Medicare prescription drug benefit plan:**

**C. Provide a copy of your organization's policies, procedures, and standards of conduct that articulate your organization's commitment to detecting and preventing waste, fraud and abuse among your Part D plans and those with whom you contract. *Provide this attachment on a CD as instructed in Section 2.4.***

**D. Identify below your organization's compliance officer, provide his/her resume, and describe his/her place in your organization (i.e., to whom does he/she directly report?):**

**E. Describe below your organization's fraud and abuse training program, including the frequency of such training:**

**F. Describe below how standards of conduct and procedures for reporting potential fraud and abuse issues are publicized within your organization:**

**G. Describe below your procedures for internal monitoring and auditing to protect the Medicare Trust Fund from waste, fraud and abuse in the Part D program (including frequency and responsible staff):**

**H. Describe below the process your staff will follow to identify possible offenses and how these matters would be reported to CMS and/or its contractors:**

### **3.11 Reporting Requirements**

**A. Complete the table below:**

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN..	YES	NO	Requesting Waiver? Yes or No
<b>BUSINESS TRANSACTIONS AND FINANCIAL REQUIREMENTS</b>			
1. Applicant will report, consistent with 42 CFR §423.514(b), information related to significant business transactions between the Part D plan sponsor and a party in interest within 120 days of the end of each fiscal year. This qualification includes combined financial statements, where required under 42 CFR §423.514(c).			
2. Applicant will notify CMS of any loans or other special financial arrangements made with contractors, subcontractors, and related entities as that term is defined in 42. CFR §423.501.			

3. Applicant will submit audited financial statements to CMS annually.			
<b>CLAIMS DATA</b>			
4. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing collection of data in either an NCPDP or X12 format. Data to be collected will encompass quantity, type, and costs of pharmaceutical prescriptions filled for enrollees. The plan must link this information to Medicare beneficiary identification numbers (HIC#s).			
5. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing submission of prescription drug claims information for Medicare enrollees for every Part D drug prescription in the format required by CMS, using batch submission processes. Data to be submitted will encompass quantity, type and costs of pharmaceutical prescriptions filled for enrollees. The plan must link this information to Medicare beneficiary identification numbers (HIC#s).			
6. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing submission of data to CMS via the Medicare Data Communications Network (MDCN) as referenced in 2.6.			
7. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing performance of data edit and quality control procedures to ensure accurate and complete prescription drug data.			
8. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing correction of all data errors identified by CMS.			
9. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing collection of data for dates of service within the coverage period with a 3-month closeout window for the submission of remaining unreported claims data.			
10. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing provision of additional information for the purposes of reconciliation of risk factors, low income subsidy payments, reinsurance payments, and risk corridor as required by CMS.			
11. Applicant will send and receive claims data for third party payers from the CMS contractor that will serve as the clearinghouse for all Part D beneficiary outpatient drug claims.			
<b>REBATE DATA</b>			
12. The Applicant or the Applicant's representative has accounting systems capable of accomplishing the provision of documentation, as specified by CMS, to support the accuracy and completeness of data. Documentation will be provided to CMS in response to an audit-based request.			
13. The Applicant will report rebate dollars on a quarterly basis at the manufacturer/brand name level (unique strength and package size not required) in the manner specified by CMS.			
14. The Applicant or the Applicant's representative has accounting systems capable of accomplishing the production of financial reports to support rebate accounting. The rebate accounting must allow for step-down cost reporting in which rebates received at the aggregate level may be apportioned down to the level of plan enrollees.			
<b>UTILIZATION MANAGEMENT DATA</b>			
15. The Applicant will report quarterly the generic dispensing rate which is calculated as the number of generic drugs dispensed to the patient divided by the total number of drugs dispensed within a given time period.			

16. If formulary management tools include prior authorization the Applicant will report to CMS on a quarterly basis information about the use of that tool. Such information may include, but is not limited to:			
<ul style="list-style-type: none"> <li>• The number of pharmacy transactions denied due to the need for prior authorization</li> <li>• The number of prior authorizations requested</li> <li>• The number of prior authorizations approved</li> </ul>			
<b>EXCEPTIONS AND APPEALS</b>			
17. The Applicant will report at a frequency specified by CMS the following information related to exceptions and appeals that may include, but is not limited to:			
<ul style="list-style-type: none"> <li>• # Step edits attempted</li> <li>• # Step edits failed</li> <li>• # Appeals</li> <li>• # Appeals overturned</li> </ul>			
<b>MEDICATION THERAPY MANAGEMENT DATA</b>			
18. The Applicant will report semi-annually (by dates to be published by CMS each year) information related to the implementation of its Medication Therapy Management program that may include, but is not limited to:			
<ul style="list-style-type: none"> <li>• # Beneficiaries targeted</li> <li>• # Beneficiaries participating</li> <li>• # Beneficiaries declined</li> <li>• Total drug cost for patients in MTM on a per enrolled MTM beneficiary per month basis</li> </ul>			
<b>OTHER DATA</b>			
19. The Applicant will provide CMS with routine administrative reports (pursuant to 42 CFR 423.514 (a)) on a variety of measures that concern the Applicant's performance in the administration of the Part D benefit. Such reports shall be submitted according to instructions issued with timely notice by CMS.			
<b>SUPPORTING <a href="http://www.Medicare.gov">WWW.MEDICARE.GOV</a></b>			
20. The Applicant will submit pricing and pharmacy network information to be publicly reported on <a href="http://www.medicare.gov">www.medicare.gov</a> in order to provide Medicare beneficiaries with necessary information regarding prescription drug costs under the respective plans. Details regarding this data requirement will be posted on <a href="http://www.cms.hhs.gov">www.cms.hhs.gov</a> by April 20, 2005.			
<b>CONFLICT OF INTEREST</b>			
21. The Applicant will provide financial and organizational conflict of interest reports to CMS, pursuant to instructions to be issued by CMS.			

Note: Further detail on our approach to monitoring and oversight, including the exact reporting measures will be posted on the CMS website not later than April 2005. Price Compare requirements will be posted in May 2005.

### **3.12 Data Exchange Between Cost Plans and CMS**

**A. Complete the table below:**

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN..	YES	NO	Requesting Waiver? Yes or No

HPMS			
1. Applicant will use HPMS to communicate with CMS in support of the application process, formulary submission process, bid submission process, ongoing operations of the Part D program, and reporting and oversight activities. Part D sponsors are required to secure access to HPMS in order to carry out these functions (See Appendix I).			
ENROLLMENT & PAYMENT			
2. Applicant will submit enrollment, disenrollment and change transactions to communicate membership information to CMS each month.			
3. Applicant will reconcile Part D sponsors data to CMS enrollment/payment reports within 45 days of availability.			
4. Applicant submits enrollment/payment attestation forms within 45 days of CMS report availability.			

### **3.13 Privacy**

#### **A. Complete the table below:**

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO	Requesting Waiver? Yes or No
1. Applicant agrees not to use the Social Security Number (SSN) or Medicare ID Number on the enrollees' identification cards.			
2. Applicant will notify each beneficiary, prior to enrollment or at the time of enrollment, of expected uses and disclosures of the beneficiary's protected health information, as well as the beneficiary's rights and Applicant's duties with respect to such information. Such notice is to be provided in plain language containing sufficient detail to advise the beneficiary of the uses and disclosures permitted or required under applicable law.			
3. Applicant will obtain written authorization for all uses and disclosures of protected health information not otherwise permitted under the HIPAA Privacy Rule. Beneficiaries may authorize disclosure of their protected health information to a third party, such as their employer.			
4. Applicant will ensure that all its agents and subcontractors comply with all the requirements of 45 CFR Parts 162 and 164 when performing functions on the Applicant's behalf.			
5. Applicant will comply with the requirements applicable to covered entities in 45 CFR Part 160 relating to use of national identifiers.			
6. Applicant will comply with any applicable standards, implementation specifications, and requirements in the Standards for Electronic Transactions under 45 CFR Parts 160 and 162 subparts I <i>et seq.</i>			

### 3.14 Claims Processing

#### A. Complete the table below:

<b>APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D ADDENDUM TO THE COST PLAN CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.</b>	<b>YES</b>	<b>NO</b>	<b>Requesting Waiver? Yes or No</b>
<p>1. Applicant develops and operates an on-line claims processing system that operates in real time to ensure accurate and timely payment of all claims submitted by network pharmacies on behalf of Part D plan enrollees. System operates according to the following standards:</p> <ul style="list-style-type: none"> <li>• 98% response within 4 seconds</li> <li>• 99% of all claims paid with no errors</li> <li>• 99% system availability</li> </ul> <p><i>Note: In preparation for implementation CMS (except for scheduled down time and disasters) will conduct testing and otherwise monitor for the impact of TrOOP system interfaces with plan claims processing systems, and adjust these standards as appropriate if necessary.</i></p>			
<p>2. Applicant develops and operates a paper claims processing system designed to pay claims submitted by non-network pharmacies on behalf of Part D plan enrollees. Applicant processes claims according to the following standards:</p> <ul style="list-style-type: none"> <li>• 100% of claims requiring no intervention handled within 15 calendar days</li> <li>• 100% of claims requiring intervention handled within 30 calendar days</li> <li>• 99% of all manually keyed claims paid with no errors</li> </ul>			
<p>3. If mail order pharmacy is offered, Applicant mail order processing meets three business day turnaround time from the point of receipt of prescription for in-stock items with no intervention to the point of shipment.</p>			
<p>4. If mail order pharmacy is offered, Applicant mail order processing meets five business day turnaround time from the point of receipt of prescription for in-stock items with intervention to the point of shipment.</p>			
<p>5. Applicant will develop and make available for CMS inspection a complete description of your claims adjudication system including:</p> <ul style="list-style-type: none"> <li>• Hardware and software</li> <li>• Operating system</li> <li>• MediSpan or First Data Bank database, including number of iterations saved</li> <li>• Number of sites processing claims (including disaster recovery back-up system)</li> <li>• System volume in covered lives, including the number of transactions the system can support per day and per hour.</li> </ul>			
<p>6. Applicant will develop and have made available to CMS upon request policies and procedures that include a complete description and flow chart detailing the claims adjudication process for each:</p> <ul style="list-style-type: none"> <li>• Contracted network pharmacies</li> <li>• Out-of-network pharmacies</li> <li>• Paper claims</li> <li>• Batch-processed claims</li> <li>• Manual claim entry (e.g. for processing direct member reimbursement)</li> </ul>			
<p>7. Applicant will develop and have made available to CMS upon request policies and procedures that include a complete description of claim detail management, including:</p> <ul style="list-style-type: none"> <li>• The length of time that detailed claim information is maintained online (not less than 12 months)</li> <li>• The data storage process after it is no longer online</li> <li>• The length of time that detailed claim information is stored when it is no longer online (not less than 10 years)</li> </ul>			

8. Applicant will develop and have available to CMS upon request policies and procedures that include a complete description of the accessibility of this information for data capture purposes and flow chart of the claims data retrieval process for each: <ul style="list-style-type: none"> <li>Entire claims history file</li> <li>Encounter data required by state mandates</li> <li>Encounter data required by alternate funding sources</li> <li>Out-of-pocket maximum/deductible files</li> </ul>			
9. Applicant will develop and have available to CMS upon request policies and procedures that include a description of how overpayments and underpayments are to pharmacies, as well as to enrollees, are handled and recovery procedures			
10. Applicant has developed and will make available to CMS upon request policies and procedures that include a complete description of procedures surrounding disputed claims, including: <ul style="list-style-type: none"> <li>The steps that a pharmacy and/or an enrollee must follow to dispute a claim reimbursement</li> <li>The average amount of time needed to resolve a claims dispute</li> <li>Turnaround time standards for dispute resolution.</li> </ul>			
11. Applicant will have a robust testing process that will identify and correct any plan configuration errors prior to implementation.			
12. Applicant will accept eligibility files and any prior claims data electronically in NCPDP format.			
13. Applicant can and will document the manner and extent to which it has tested benefit designs such as drug exclusions or quantity limitations and plan parameters such as co-payments or benefit maximums.			

### **3.15 Security and Record Retention**

#### **A. Complete the table below:**

<b>APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:</b>	<b>YES</b>	<b>NO</b>	<b>Requesting Waiver? Yes or No</b>
<b>SECURITY</b>			
1. Applicant attests that at least one of the following conditions is true: a) By completing the <i>HIPAA Security Attestation Statement</i> , (Appendix V), as of the initial enrollment date, appropriate administrative, technical, and physical safeguards will be in place to protect the privacy of protected health information in accordance with 45 CFR §164.530(c), and that Applicant will meet the standards, requirements, and implementation specifications as set forth in 45 CFR part 164, subpart C, the HIPAA Security Rule, prior to beginning enrollment of beneficiaries; or b) If Applicant is unable to provide this attestation, Applicant provides a plan for coming into compliance with the specifications as set forth in the Security Rule as requested in 3.16B below. Applicant is encouraged, but not required, to use the Information Security Program references as provided by the National Institute of Standards and Technology (NIST) found at <a href="http://www.nist.gov">www.nist.gov</a> in describing your efforts to implement reasonable security measures.			
<b>RECORD RETENTION</b>			
2. The Applicant will maintain, for 10 years, books, records, documents, and other evidence of accounting procedures and practices consistent with 42 CFR §423.505(d).			

**B. If Applicant does not attest to being in compliance with the HIPAA security provisions as stated in 3.16A1, then complete and provide *Plan to Come into Compliance with HIPAA Security Requirements* (Appendix VI)**

## 4.0 CERTIFICATION

I, the undersigned, certify to the following:

- 1) I have read the contents of the completed application and the information contained herein is true, correct, and complete. If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Centers for Medicare & Medicaid Services (CMS) immediately and in writing.
- 2) I authorize CMS to verify the information contained herein. I agree to notify CMS in writing of any changes that may jeopardize my ability to meet the qualifications stated in this application prior to such change or within 30 days of the effective date of such change. I understand that such a change may result in termination of the approval.
- 3) I agree that if my organization meets the minimum qualifications and is Medicare-approved, and my organization enters into a Part D contract with CMS, I will abide by the requirements contained in Section 3.0 of this Application and provide the services outlined in my application.
- 4) I agree that CMS may inspect any and all information necessary including inspecting of the premises of the Applicant's organization or plan to ensure compliance with stated Federal requirements including specific provisions for which I have attested. I further agree to immediately notify CMS if despite these attestations I become aware of circumstances which preclude full compliance by January 1, 2006 with the requirement stated here in this application as well as in Part 423 of 42 CFR of the regulation.
- 5) I understand that in accordance with 18 U.S.C. § 1001, any omission, misrepresentation or falsification of any information contained in this application or contained in any communication supplying information to CMS to complete or clarify this application may be punishable by criminal, civil, or other administrative actions including revocation of approval, fines, and/or imprisonment under Federal law.
- 6) I further certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to enter into a Part D addendum to my organization's Medicare Cost Plan contract with CMS.

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Authorized Representative Name (printed)

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Title

---

Authorized Representative Signature

---

Date (MM/DD/YYYY)

## 5.0 APPENDICES

### APPENDIX I

#### Instructions for Accessing CMS Systems Health Plan Management System (HPMS)

Cost plans will be required to use HPMS to carry out various CMS Part D functions, including the application process, formulary submission process, bid submission process, ongoing operations of the Part D program, and reporting and oversight activities. Cost plans will need the following to access HPMS:

- (1) Internet or Medicare Data Communications Network (MDCN) connectivity,
- (2) Use of a Microsoft Internet Explorer web browser (version 5.1 or higher) with 128-bit encryption, and
- (3) A CMS-issued user ID and password with access rights to HPMS for each user within the cost plan organization who will require such access.

Applicants should access the CMS website at <http://www.cms.hhs.gov/mdcn/access.pdf> to obtain the latest version of the "Application for Access to CMS Computer Systems" form. In addition to completing each section of the form, as appropriate, the cost plan user should: 1) check "**Mgd Care Org/Group Health Plan**" in Section 2, and 2) write **HPMS** on the first blank line in Section 3a. The cost plan user should also include their contract number in Section 2h.

**In order to expedite the processing of this request, CMS strongly recommends that organizations refrain from requesting any additional systems access other than HPMS on this particular form submission at this time. You must also sign and date page 2 containing the Privacy Act statement and return it along with the form. Your request cannot be processed without this signature and date. The original signed form (both pages) must be mailed to the following address:**

Centers for Medicare & Medicaid Services  
Attention: Marietta Mack  
Mail Stop S1-25-13 / Location S2-04-05  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

Please contact Don Freeburger (410-786-4586 or [DFreeburger@cms.hhs.gov](mailto:DFreeburger@cms.hhs.gov)) or Greg Buglio (410-786-6562 or [GBuglio@cms.hhs.gov](mailto:GBuglio@cms.hhs.gov)) with any questions about completing this form. CMS will provide you with additional technical instructions on accessing HPMS, including its website address, once your user ID has been processed.

#### **Important Note for Current HPMS Users**

If your organization already has access to HPMS, you do not need to request new CMS user IDs unless you need to obtain HPMS access for new cost plan users at your organization.

#### **Other CMS Systems**

Applicants will also be required to obtain access to other CMS systems in order to perform necessary operational functions, including, but not limited to, enrollment and claims submission. Instructions for obtaining access to those other systems will be provided to Applicants separately.

## APPENDIX II

### Banking Information Form

As Government vendors, organizations with Medicare contracts are paid by the Department of Treasury through an Electronic Funds Transfer (EFT) program. Government vendor payments are directly deposited into corporate accounts at financial institutions on the expected payment date. Additionally, CMS must have the EIN/TIN and associated name as registered with the IRS.

Please provide the following information to assist the Centers for Medicare and Medicaid Services in establishing payment arrangements for your organization.

#### ORGANIZATION INFORMATION

Name of Organization:	DBA, if any:
Full Address of Organization ( <i>Street, City, Zip</i> ):	
Contact Person Name:	Telephone Number:
Contract Numbers, if known:	
Employer/Tax Identification Number (EIN/TIN):	
EIN/TIN Name ( <i>Name of Business for tax purposes as registered with the IRS</i> ): <i>A W-9 may be required</i>	
Full Address for 1099 Tax Form ( <i>Street, City, Zip</i> ):	

#### FINANCIAL INSTITUTION

Name of Bank:	
Full Address of Bank ( <i>Street, City, Zip</i> ):	
ACH/EFT Coordinator Name:	Telephone Number:
Nine Digit Routing Transit (ABA Number):	
Depositor Account Title:	
Depositor Account Number:	
Check Account Type: ( <i>Please Attach a Copy of A Voided Check</i> ) <input type="checkbox"/> Checking <input type="checkbox"/> Savings	

#### SIGNATURE & TITLE OF ORGANIZATION'S AUTHORIZED REPRESENTATIVE

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Title: \_\_\_\_\_

Print Name: \_\_\_\_\_

Phone Number: \_\_\_\_\_

## APPENDIX III

### Pharmacy Access Standards

#### § 423.120 Access to Covered Part D Drugs

##### (a) Assuring pharmacy access.

(1) Standards for convenient access to network pharmacies. Except as provided in paragraph (a) (7) of this section, a Part D plan must have a contracted pharmacy network, consisting of retail pharmacies sufficient to ensure that for beneficiaries residing in each State in the prescription drug plan's service area, (as defined in § 423.112 (a)), each State in a regional MA-PD plan's service area, (as defined in § 422.2 and § 422.455 (a) of this chapter), a local MA-PD plan's service area (as defined in § 422.2 of this chapter), or a cost plan's geographic area (as defined in § 417.401 of this chapter), the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the Part D plan live within 2 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a) (2) of this section;

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the Part D plan live within 5 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a) (2) of this section; and

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the Part D plan live within 15 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a) (2) of this section.

(2) Applicability of some non-retail pharmacies to standards for convenient access. Part D plans may count I/T/U pharmacies and pharmacies operated by Federally Qualified Health Centers and Rural Health Centers toward the standards for convenient access to network pharmacies in paragraph (a) (1) of this section.

## APPENDIX IV

### Summary of PDP Application Requirements Waived for Cost Plan Prescription Drug Applicants

Part D Regulation Waived	Regulatory Requirement(s) Description	Basis and Rationale
<b>42 CFR 423 Subpart I, excepting 42 CFR 423.440 ( which concerns Federal preemption of State law and prohibition of State premium taxes)</b>	Licensure and Solvency – Applicant must be licensed to bear risk in the State in which it intends to operate or apply for a licensure waiver and meet CMS solvency standards.	Duplicative of Cost Plan requirements for licensure and solvency under 42 CFR §417.404 (General requirements) and 42 CFR 417.407 (Requirements for a Competitive Medical Plan (CMP)). All cost plans are State licensed in some manner or have authority to offer a cost plan in all states in which they operate.
<b>42 CFR 423.112 (a)</b>	Service Area – Applicant must offer a Part D plan that serves at least an entire PDP region.	Conflicts with Cost plan regulations (42 CFR 417.1) defining the service area for HMOs and CMPs offering Medicare reasonable cost plans.
<b>42 CFR 423.120(a)(3) <i>Waiver applies only to Cost contractors that operate their own pharmacies</i></b>	Pharmacy Network – Applicant must offer its Part D plan benefit through a contracted retail pharmacy network that meets CMS standards for convenient access.	Waiver stated in regulations at 42 CFR 423.120(a)(7)(i) excuses from the CMS standards for convenient access those Cost contractors that administer their Part D benefit through pharmacies owned by the Cost contractor if that organization's pharmacy network access is comparable to the CMS convenient access standards . <i>{Note: Applicants will be expected to provide comparable information in the application for organizational pharmacies}</i>

## APPENDIX V

### CERTIFICATION OF MONTHLY ENROLLMENT AND PAYMENT DATA RELATING TO CMS PAYMENT TO A COST PLAN

Pursuant to the contract(s) between the Centers for Medicare and Medicaid Services (CMS), and \_\_\_\_\_ (*name of Cost Plan*) hereafter referred to as the "Prescription Drug Plan" governing the operation of the following Cost Plans \_\_\_\_\_ (*plan identification numbers*), the Cost Plan hereby requests payment under the contract, and in doing so, makes the following certifications concerning CMS payments to the Cost Plan. The Cost Plan acknowledges that the information described below directly affects the calculation of CMS payments to the Cost Plan and that misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution. This certification shall not be considered a waiver of the Cost Plan's right to seek payment adjustments from CMS based on information or data that does not become available until after the date the Cost Plan submits this certification.

1. The Cost Plan has reported to CMS for applications received in the month of \_\_\_\_\_ (*month and year*) all new enrollments, disenrollments, and changes in Plan Benefit Packages with respect to the above-stated Cost Plans. Based on best knowledge, information, and belief, all information submitted to CMS in this report is accurate, complete, and truthful.
2. The Cost Plan has reviewed the CMS monthly membership report and reply listing for the month of \_\_\_\_\_ (*month and year*) for the above-stated Cost Plans and has submitted requests to the IntegriGuard, under separate cover, for retroactive adjustments to correct payment data when the Cost Plan has more accurate information. This may include enrollment status and State and County Code related to specific beneficiary. For those portions of the monthly membership report and the reply listing to which the Cost Plan raises no objection, the Cost Plan, through the certifying CEO/CFO, will be deemed to have attested, based on best knowledge, information, and belief, to their accuracy, completeness, and truthfulness.

NAME: \_\_\_\_\_

TITLE: \_\_\_\_\_

On behalf of: \_\_\_\_\_ (*Cost Plan*)

NOTE: The person signing this form must be the CEO, CFO, or an individual delegated the authority to sign on behalf of on of the CEO or CFO and who reports to the CEO or CFO. Otherwise the certification will be considered invalid, per CFR 423.505 (k).

## APPENDIX VI

### Plan to Come into Compliance with HIPAA Security Requirements

Modified from HIPAA Security Rule Appendix A to Subpart C to Part 164<sup>3</sup> -- Security Standards: Matrix

Complete the tables below using this example:

Standards	Sections	Implementation Specifications (R)=Required, (A)= Addressable		Project / Activity	Scheduled Completion
Security Awareness and Training	164.308(a)(5)	Security Reminders	(A)	Perform gap analysis, develop awareness program	3Q CY 2005
		Protection from Malicious Software	(A)		
		Log-in Monitoring	(A)		
		Password Management	(A)		

### ADMINISTRATIVE SAFEGUARDS (see § 164.308)

Standards	Sections	Implementation Specifications (R)=Required, (A)= Addressable		Project/Activity	Scheduled Completion
Security Management Process	164.308(a)(1)	Risk Analysis	(R)		
		Risk Management	(R)		
		Sanction Policy	(R)		
		Information System Activity Review	(R)		
Assigned Security Responsibility	164.308(a)(2)		(R)		
Workforce Security	164.308(a)(3)	Authorization and/or Supervision	(A)		
		Workforce Clearance Procedure	(A)		
		Termination Procedures	(A)		
Information Access Management	164.308(a)(4)	Isolating Health Care Clearinghouse Function	(R)		
		Access Authorization	(A)		
		Access Establishment and Modification	(A)		
Security Awareness and Training	164.308(a)(5)	Security Reminders	(A)		
		Protection from Malicious Software	(A)		
		Log-in Monitoring	(A)		
		Password Management	(A)		
Security	164.308(a)(6)	Response and Reporting	(R)		

<sup>3</sup> 45 CFR parts 160, 162 and 164 Health Insurance Reform: Security Standards; Final Rule

Incident Procedures					
Contingency Plan	164.308(a)(7)	Data Backup Plan	(R)		
		Disaster Recovery Plan	(R)		
		Emergency Mode Operation Plan	(R)		
		Testing and Revision Procedure	(A)		
		Application and Data Criticality Analysis	(A)		
Evaluation	164.308(a)(8)		(R)		
Business Associate Contracts and other Arrangement	164.308(b)(1)	Written Contract or Other Arrangement	(R)		

**PHYSICAL SAFEGUARDS (see § 164.310)**

Standards	Sections	Implementation Specifications (R)=Required, (A)= Addressable		Project	Scheduled Completion
Facility Access Controls	164.310(a)(1)	Contingency Operations	(A)		
		Facility Security Plan	(A)		
		Access Control and Validation Procedures	(A)		
		Maintenance Records	(A)		
			(R)		
Workstation Use	164.310(b)		(R)		
Workstation Security	164.310(c)		(R)		
Device and Media Controls	164.310(d)(1)	Disposal	(R)		
		Media Re-use	(R)		
		Accountability	(A)		
		Data Backup and Storage	(A)		

### TECHNICAL SAFEGUARDS (see 164.312)

Standards	Sections	Implementation Specifications (R)=Required, (A)=Addressable		Project	Scheduled Completion
Access Control	164.312(a)(1)	Unique User Identification	(R)		
		Emergency Access Procedure	(R)		
		Automatic Logoff	(A)		
		Encryption and Decryption	(A)		
Audit Controls	164.312(b)		(R)		
Integrity	164.312(c)(1)	Mechanism to Authenticate Electronic Protected Health Information	(A)		
Person or Entity Authentication	164.312(d)		(R)		
Transmission Security	164.312(e)(1)	Integrity Controls	(A)		
		Encryption	(A)		

## CERTIFICATION THAT SUBCONTRACTS MEET THE REQUIREMENTS OF SECTION 3.1.1D

A. I, the undersigned, certify, on behalf of LEGAL NAME, to the following:

The contracts submitted as attachments to Section 3.1.1:

1. Clearly identify the parties to the contract (or letter of agreement);
2. Describe the functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.1B of the application;
3. Contain language clearly indicating that the subcontractor has agreed to participate in your Medicare Prescription Drug Benefit program (except for a network pharmacy if the existing contract would allow participation in this program), and flow-down clauses requiring their activities be consistent and comply with the Applicant's contractual obligations as a PDP sponsor;
4. Contain language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program;
5. Describe the payment the subcontractor will receive for performance under the contract, if applicable;
6. Are for a term of at least the first year of the program (i.e., January 1, 2006 through December 31, 2006);
7. Are signed by a representative of each party with legal authority to bind the entity;
8. Contain language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions;
9. Contain language obligating the subcontractor to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136;
10. Contain language ensuring that the subcontractor will make their books and other records available in accordance with 42 CFR §423.505(i)(2), which generally states these regulations give HHS, the Comptroller General, or their designees the right to inspect, evaluate and audit books and other records and that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later;
11. Contain language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant;
12. Contain language stating that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the subcontractor, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the subcontractor has not performed satisfactorily. The subcontract may include remedies in lieu of revocation to address this requirement;
13. Contain language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the subcontractor on an ongoing basis; and
14. Contain language that the Part D sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy if the subcontractor will establish the pharmacy network or select pharmacies to be included in the network.

B. I certify that I am authorized to sign on behalf of the Applicant.

C. I understand that CMS will review the submitted contracts to ensure that they comply with the contracting requirements stated in Section 3.1.1D of the Solicitation for Applications from Prescription Drug Plans (PDPs)/Medicare Advantage Prescription Drug Plan Sponsors/Cost Plan Sponsors. When a submitted contract does not meet a requirement, CMS will ask the Applicant to resubmit the contract in question. I understand the Applicant's failure to provide in a timely manner fully executed contracts that meet CMS requirements may affect CMS' decision to allow the Applicant to accept enrollment into its Part D plan(s) on November 15, 2005.

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Authorized Representative Name (printed)

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Title

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Authorized Representative Signature

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Date (MM/DD/YYYY)

**Appendix VII**  
**Citations of Subcontracts Submitted as attachments to Section 3.1.1D**

<b>INSTRUCTIONS:</b> Applicants must complete the following chart for each subcontractor submitted under Section 3.1.1D.		
Applicants must identify where in each contract the following elements may be found.		
<b>Section</b>	<b>Requirement</b>	<b>Citation</b>
3.1.1D1	The parties to the contract	
3.1.1D2	The functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.1B of the application.	
3.1.1D3	Language clearly indicating that the subcontractor has agreed to participate in your Medicare Prescription Drug Benefit program (except for a network pharmacy if the existing contract would allow participation in this program), and flow-down clause.	
3.1.1D4	Language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program.	
3.1.1D5	The payment the subcontractor will receive for performance under the contract, if applicable.	
3.1.1D6	Are for a term of at least the first year of the program.	
3.1.1D7	Are signed by a representative of each party with legal authority to bind the entity.	
3.1.1D8	Language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions.	
3.1.1D9	Language obligating the subcontractor to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
3.1.1D10	Language ensuring that the subcontractor will make their books and other records available in accordance with 42 CFR §423.505(i)(2), which generally states these regulations give HHS, the Comptroller General, or their designees the right to inspect.	
3.1.1D11	Language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant.	
3.1.1D12	Language stating that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the subcontractor, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the subcontractor has not performed satisfactorily. The subcontract may include remedies in lieu of revocation to address this requirement.	
3.1.1D13	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the subcontractor on an ongoing basis.	
3.1.1D14	Language that the Part D sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy if the subcontractor will establish the pharmacy network or select pharmacies to be included in the network.	

**APPENDIX VIII**  
Citations for Pharmacy Access Contracts

<b>INSTRUCTIONS:</b> Applicants must complete the following chart (which contains applicable Section 3.1.1 D requirements AND additional requirements specific to Pharmacy Access, Long-Term Care and I/T/U contracts) for each pharmacy contract submitted under Section 3.3. Applicants must identify where in each contract the following elements reside.		
<b>Indicate the type of pharmacy to which contract applies:</b>  <input type="checkbox"/> Retail <input type="checkbox"/> Mail Order <input type="checkbox"/> Home Infusion <input type="checkbox"/> Long-Term Care <input type="checkbox"/> I/T/U (for IHS contracting) <input type="checkbox"/> I/T/U (for tribal contracting)		
<b>The provisions listed below must be in all pharmacy contracts. If contracts reference policies and procedures to which the pharmacy must abide, provide the relevant documentation as evidence and cite this documentation accordingly.</b>		
Section	Requirement	Citation
3.1.1D2	The functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.1B of the application.	
3.1.1D4	Language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program.	
3.1.1D8	Language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions.	
3.1.1D9	Language obligating the subcontractor to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	
3.1.1D10	Language ensuring that the subcontractor will make their books and other records available in accordance with 42 CFR §423.505(i)(2), which generally states these regulations give HHS, the Comptroller General, or their designees the right to inspect.	
3.1.1D11	Language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant.	
3.1.1D12	Language stating that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the subcontractor, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the subcontractor has not performed satisfactorily. The subcontract may include remedies in lieu of revocation to address this requirement.	
3.1.1D13	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the subcontractor on an ongoing basis.	
3.3A3	Applicant's network pharmacy contracts contain provisions governing submitting claims to a real-time claims adjudication system.	

	Note: Applicant may indicate for I/T/U pharmacies and for certain pharmacies that are allowed to submit claims in this X12 format that these may be batch processed.	
3.3A4	Provisions governing providing access to negotiated prices.	
3.3A5	Provisions regarding charging/applying the correct cost-sharing amount, including that which applies to individuals qualifying for the low-income subsidy.	
3.3A6	Provisions governing informing the Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price.	
<b>Elements Specific to Long-Term Care Contracts</b>		
<b>Note: CMS will release Long-Term Care Guidance in early March 2005. This document will contain an updated list of performance and service criteria as referenced in Item #1 of 3.4.5A. Applicants will be required to incorporate at a minimum, these criteria in any LTC pharmacy network contract. Applicant must list the criteria below, and then identify where the element is met in the contract.</b>		
	<b>Performance/Service Criteria</b>	<b>Citation</b>
<b>Elements Specific to Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacy Contracts</b>		
<b>Note: Sections referenced are the provisions listed in the I/T/U and HIS Model Addenda located at <a href="http://www.cms.hhs.gov/pdps/">http://www.cms.hhs.gov/pdps/</a> and <a href="http://www.cms.hhs.gov/aian/">http://www.cms.hhs.gov/aian/</a>. The I/T/U Contracts must contain language consistent with the model tribal pharmacy and IHS addenda that address the following</b>		
Item 3	Description of the provider.	
Item 4	Counting of costs paid for by provider toward any deductibles.	
Item 5	Persons eligible for services of the provider.	
Item 6	The applicability of certain Federal law.	
Item 7	The non-taxable status of the provider (only in contracts with tribal pharmacies)	
Item 8	Insurance and indemnification.	
Item 9	Applicability of state licensing law to provider's employees.	
Item 10 (I/T/U only)	Provider eligibility for payments (only in contracts with tribal pharmacies).	
Item 11 (I/T/U) & Item 10 (IHS)	Dispute resolution.	
Item 12 (I/T/U) & Item 11 (IHS)	Federal law as the governing law.	

Item 13 (I/T/U) & Item 12 (IHS)	The contract will apply to all pharmacies and dispensaries operated by the provider.	
Item 14 (I/T/U) & Item 13 (IHS)	The contract will not affect the provider's acquisition of pharmaceuticals.	
Item 15 (I/T/U) & Item 14 (IHS)	The provider's point of sale processing capabilities.	
Item 16 (I/T/U) & Item 15 (IHS)	Claims processing.	
Item 17 (I/T/U) & Item 16 (IHS)	Reasonable and appropriate payment rates.	
Item 18 (I/T/U) & Item 17 (IHS)	Any information, outreach or enrollment materials prepared by the Applicant will be supplied at no cost to the provider.	
Item 19 (I/T/U) & Item 18 (IHS)	The provider determines the hours of service for the pharmacies or dispensaries of the provider.	
Item 19 (IHS only)	The contract will not be an official or implied endorsement by IHS or IHS employees (applicable only to IHS contract).	